APPENDIX D

PORTABLE X-RAY SERVICES

INTEPRETIVE

GUIDELINES

APPENDIX D

Interpretive Guidelines - Portable X-Ray Services

Conditions of Coverage

Condition I	COMPLIANCE WITH FEDERAL, STATE AND LOCAL LAWS (405.1411)
Condition II	SUPERVISION BY A QUALIFIED PHYSICIAN (405.1412)
Condition III	QUALIFICATION AND ORIENTATION OF TECHNICAL PERSONNEL AND EMPLOYEE RECORDS (405.1413)
Condition IV	REFERRAL FOR SERVICE AND PRESERVATION OF RECORDS (405.1414)
Condition V	SAFETY STANDARDS (405.1415)
Condition VI	INSPECTION OF EQUIPMENT (405.1416)

INTERPRETATION AND EXPLANATION OF CONDITIONS FOR COVERAGE

In view of the inherent danger in the use of X-rays, especially when they are being used without the direct personal supervision of a physician, strict standards have been set up for coverage of portable X-rays under the Medicare program. Accordingly, suppliers must meet all standards in each condition to qualify. In other words, if one standard is not met, the supplier of portable X-ray services must be certified as not in compliance with the Conditions for Coverage. Coverage services are defined in Regulation 42 CFR 405.1401(c).

Condition for Coverage I (§405.1411) - Compliance with Federal, State and Local Laws.--The supplier, its equipment and personnel must be licensed or registered in accordance with applicable Federal, State and local laws. Review licenses and registration permits to confirm their validity and currency.

X-ray equipment manufactured on or after August 1, 1974 must bear a label indicating it meets FDA standards. If equipment found in use is different from what was described to the SA prior to survey, note the name of the manufacturer, equipment model number, serial number, and date of manufacturer (if shown) so that this can be checked out after the survey. Do not show a deficiency unless it has been definitely ascertained that the equipment does not meet FDA standards.

Condition for Coverage II (§405.1412) - Supervision by a Qualified Physician.
--The performance of X-ray tests is subject to the supervision of a physician qualified by advanced training and experience in use of diagnostic X-rays regardless whether the physician owns the equipment or not. In the event the supervising physician is not listed as the owner and the physician certification required in Standard (a) has not been submitted with the Request for Approval, HCFA-1880, request such certification at survey. Since Standard (a) requires an annual certification by a supervising physician if he is not the owner, ask the supplier to have the certification for the current year available at the time of survey to prevent any delay in certification (see Exhibit lC.)

To confirm that a physician-supervisor specializes in radiology and is recognized by the medical community as a specialist in radiology (Standard (b)), the record should reflect that the physician is (1) board certified or board eligible in radiology; (2) board certified or board eligible in a medical specialty which includes advanced training in use of X-rays, e.g., The American Board of Orthopedic Surgery, the American Board of Internal Medicine, The American Board of Physical Medicine and Rehabilitation and The Board of

Thoracic Surgery, or (3) recognized by the medical community as a specialist in radiology. Check the American Medical Directory or the Dictionary of Medical Specialists for (l) and (2). To substantiate (3), the record should show how much of the physician's practice is devoted to radiology as well as what other specialties he practices, and the basis for recognition as a specialist by the medical community; i.e., do other physicians regularly refer radiology work to him, and does he have arrangements with local hospitals to provide radiology services or act as a radiology consultant.

Condition for Coverage III (§405.1413) - Qualifications and Orientation of Technical Personnel and Employee Records.--Diplomas, resumes and other records maintained by the supplier or where applicable, in State licensure records, show that a particular academic or training requirement has been met. In the absence of such documentary evidence, request that the individuals involved arrange to have the school or physician involved in attesting to the academic or experience qualifications mail this documentation directly to the SA. Ascertain the methods of staff member orientation and also check the procedural manual for content to ensure that it includes all factors cited in the Survey Report.

If a supplier uses the services of a non-physician equipment operator, interview that individual to assess his/her functions, duties, responsibilities and the degree of supervision he/she receives. Review policies and procedures, records of examinations the operator has taken, and records and reports of inspections of equipment.

Conditions for Coverage IV (§405.1414) - Referral for Services and Preservation of Records.--The supplier's records showing that X-ray tests were ordered in writing by a physician licensed to practice in the State are essential to establish that the standards are met. Follow up within a reasonable period (i.e., 90 days) to recheck the supplier's records for compliance with this important standard.

While section 405.1414(a)(2) is explicit as to the type of information that is required in a physician's request, there may be some leeway granted in initial survey in this area. If all pertinent information has been furnished to the supplier, but was simply not retained or recorded by the supplier, the standard may be considered as met. However, inform the supplier of the need in the future to obtain specific data as cited in the regulations. This leeway is to be granted only temporarily, and is not to be interpreted as relaxation of the requirement that all standards must be met.

The supplier's patient records should be checked for the information specified in section 405.l4l4(b). If past records are not consistently complete as to the required data, the supplier should be informed of the need to establish a system of recordkeeping that will conform to the regulations. If it is found that no records have been kept, the supplier should be informed that a recheck will be made in 30 days to insure that it is in compliance with this requirement. The surveyor should inform the supplier of the need for keeping records for a period of at least 2 years, or for the period of time required by State law, whichever is longer.

Condition for Coverage V (42 CFR 405.l4l4) - Safety Standards.--Each of the eleven safety standards, if applicable, must be met to find a supplier in compliance. Where a State or local radiation health inspection program conducted a survey within l2 months of the Medicare survey and such inspection reveals compliance with all applicable safety standards, such State or local investigation will satisfy initial compliance with this regulation. However, if any equipment, operating procedures, or shielding was noted as constituting a potential hazard, it must be corrected before recommending approval. Also, if the State inspection did not completely cover each applicable standard, the inspection report is acceptable only for that portion covered and the surveyor would be responsible for evaluating the pertinent standards not covered in the previous inspection.

Where deficiencies are found to exist at the time of survey, the supplier should be informed that corrective action is necessary within 30 days and that he must submit proof that correction has been made.

Condition for Coverage VI (42 CFR 405.l4l6) - Inspection of Equipment.--If State records or suppliers records fail to indicate that State or local radiation health inspection have been performed within 24 months of the Medicare survey, the survey for Medicare purposes of the supplier by a qualified inspector will satisfy this requirement.

APPENDIX E

OUTPATIENT PHYSICAL THERAPHY

OR

SPEECH PATHOLOGY SERVICES

INTERPRETATIVE

GUIDELINES

Appendix E

Interpretive Guidelines

Outpatient Physical Therapy or Speech Pathology Services

Conditions of Participation

Explanation of Conditions of Participation for
Providers of Outpatient Physical Therapy or Speech Pathology Services

I. COMPLIANCE WITH FEDERAL, STATE AND LOCAL LAWS (42 CFR 405.1715)

A. General.--In order to assure that the clinic, rehabilitation agency, or public health agency and staff are in possession of current licenses as required by Federal, State and local laws, licenses should be available for review. Compliance with this Condition may have a direct bearing on other Conditions; e.g., physical therapy services (405.l7l8), speech pathology services (405.l7l9), rehabilitation program (405.l720), and physical environment (405.l723).

B. Major Sources of Information

- Federal, State and local laws governing health care; building, fire and safety codes

- Applicable State and local licenses and organization personnel records containing up-to-date information

- Written policies pertaining to communicable and reportable diseases, conforming to applicable Federal, State and local laws

C. Standards

Standard (a): Licensure of Organization.--Where State law provides for the licensing of clinics, rehabilitation agencies, public health agencies or similar facilities which meet the definitions contained in 405.1702, verify at the time of the survey that a current license is valid and in effect. A license must be in effect before the organization can be certified to participate in the program. Where a license for an organization currently participating has been temporarily suspended or revoked, contact the appropriate State department or authority to ascertain the status of the organization's licensure. If a license is not to be issued, initiate termination proceedings.

In the event the organization is out of compliance with State requirements and the appropriate State authority does not take the action necessary to revoke the license, do not initiate termination proceedings solely on the basis of noncompliance with 405.1715. If, however, such noncompliance results in other Conditions being not met, initiate termination citing all Conditions not met, including 405.1715.

Some States may issue provisional licenses. Where this is the case, document the reason(s) for such status and, most importantly, any limitation(s) imposed on the services rendered as a result. Contact the appropriate State department or authority and obtain information concerning the length of time

the provisional status is to be in effect. If the limitations stipulated in a provisional license adversely affect the ability to render services in compliance with regulations, another Condition may be not met; in that case, initiate termination if those restrictions are to remain in force.

Standard (b): Licensure or Registration of Personnel.--Review facility records, a central State listing, or other evidence of current licensure or registration of personnel, such as wallet size identification cards sometimes made available. Where personnel are required to be licensed but are not, notify the appropriate State licensing body(ies).

II. ADMINISTRATIVE MANAGEMENT (42 CFR 405.1716)

A. General.--The clinic or rehabilitation agency has a governing body, or designated persons so functioning, responsible for its policies and operations. The provision of adequate and effective services requires that the clinic or rehabilitation agency be responsive to internal and external needs and demands which may necessitate changes in program operation.

B. Major Sources of Information

- o Articles of incorporation, bylaws, policy statements, etc.
- o Minutes of governing body; staff and patient care policy committee meetings
- o Organizational chart showing administrative framework
- o Personnel records--employee qualifications and licenses
- o Patient care policies
- o Clinical records

C. Standards

Standard (a): Governing Body.--The governing body is the board of directors or trustees of a corporation, the owner(s) in the case of a proprietary clinic or rehabilitation agency, or others who have legal responsibility for the operation of the clinic or rehabilitation agency. It is not inappropriate for employees of an incorporated clinic or rehabilitation agency to also serve as members of the governing body.

The names and addresses of all individuals having legal responsibility for the clinic or rehabilitation agency should be available on the provider's HCFA-1513.

Assess the governing body on its effectiveness in providing guidance and direction for the clinic or rehabilitation agency in such terms as program stability and adequacy and in carrying out its legal responsibilities. Certain written provisions should appear in the bylaws or equivalent, specifying:

- The basis upon which members of the governing body are selected (where applicable), their terms of office, and their duties and responsibilities;

- To whom responsibilities for direction of the program and evaluation of practices may be delegated, and the methods established by the governing body for holding appropriate individuals responsible; and

- The frequency of governing body meetings and that minutes be kept.

Standard (b): Administrator:--The administrator who does not possess the required experience or specialized training in the administration of an outpatient physical therapy provider (rehabilitation agency, clinic, public health agency) may use training or experience acquired in the management or supervision of health institutions and agencies similar in scope to an outpatient physical therapy provider. College-level courses in health services administration and management approved by the appropriate State authority would meet the necessary requirements for specialized training.

The administrator should be familiar with all aspects of the operation of the clinic or rehabilitation agency such as scope of services provided, budgetary and fiscal matters, personnel, and other areas necessary to effectively direct operational activities. The administrator is also responsible for coordinating staff education, sometimes referred to as inservice education, or continuing education. In this regard, the administrator should see that each employee has the opportunity to increase the skills and knowledge necessary to promote effective and efficient patient care. Review listing of inservice program content, type of instruction (e.g., lecture or demonstration), dates of instruction, and attendees.

When the administrator is unable to carry out delegated duties, a similarly qualified alternate is to be readily available (on the premises or by telephone) at all times during operating hours to assume the administrator's responsibilities. Verify that such an individual has been selected.

Standard (c): Personnel Policies.--Personnel policies should generally address the relationship between the facility administration and facility staff, e.g., how the administration governs the conduct and performance of its employees, and its responsibility to its staff. During interviews with the facility administrator and staff, elicit evidence that personnel practices are based on written personnel policies. For example, if the facility administration conducts performance evaluations on its staff, do written personnel policies address how and when the evaluations are conducted?

Standard (d): Patient Care Policies.--Patient care policies are established by the professional staff of the clinic or rehabilitation agency and outside professionals, where appropriate, who function as a patient care policy committee. Review minutes of meetings to determine whether the policies of the clinic or rehabilitation agency are current and responsive to the needs of patients, and whether, when unresponsive, appropriate policy revisions are undertaken.

Review the written patient care policies and determine whether the facility operates in conformity with them.

III. PLAN OF CARE AND PHYSICIAN INVOLVEMENT (42 CFR 405.1717)

A. General.--All patients must be treated pursuant to a written plan of care that indicates anticipated goals and specifies the type, amount, frequency, and duration of services to be furnished. Non-Medicare patients are neither required to be under the care of a physician nor have a plan of care established by a physician.

B. Major Sources of Information.

- Patients' plans of care
- Emergency procedures
- Patient care policies
- Clinical records

C. Standards

Standard (a): Medical History and Prior Treatment.--The regulations do not require the patient be referred to the facility by a physician or that the services are furnished pursuant to a physician's orders. However, since Medicare patients are still required under the statute to be under the care of a physician and have the plan of care periodically reviewed by a physician to receive payment for Medicare covered services, current medical findings, diagnosis(es), physician's orders, rehabilitation goals and contraindications would normally be made available to the facility by the attending physician. Non-Medicare patients are not required to be under the care of a physician, have a plan of care established by a physician and have the plan of care periodically reviewed by a physician. When reviewing patients' records, if you find a referral from a physician for a non-Medicare patient do not cite a deficiency if the referral fails to include the specified items. When complete and appropriate past history along with current medical findings are not made available to the organization, the organization should obtain the information either from the patient or from followup with the referring physician, if any.

Standard (b): Plan of Care.--When you review a patient's record to determine if a plan of care has been established and is periodically reviewed, it is not necessary to establish whether the patient is a Medicare or non-Medicare patient. The condition statement and standard permit, for each patient, the plan of care to be established by a physician, or by the appropriate professional (i.e., a physical therapist or speech pathologist) and reviewed by a physician or the individual who established it. However, as a condition for Medicare payment, a physician must certify the necessity of the services and review the plan of care every 30 days for each Medicare patient to recertify the continued need for those services. This review by the physician will probably be the review the facility uses for Medicare patients to meet the Condition of Participation. Since Medicare patients must be under the care of a physician for purposes of receiving payment for Medicare covered services, this attending physician must be notified of any changes in the plan of care or the patient's condition.

NOTE: The term physician includes a podiatrist whose performance of functions are consistent with the OPT's policy and whose services are related to functions he/she is legally authorized to perform.

If after patient treatment has begun, a professional furnishing care changes current treatment, the change requires a revision in the plan of care and must be supported in the patient's clinical record by either documentation by the professional, a dated written order signed by the physician, or a dated verbal order signed by the professional receiving the order.

Standard (c): Emergency Care.--Verify that the names and telephone numbers are readily available for the physician(s) the organization has arranged to be on call to provide medical care in case of an emergency during operating hours. Review the medical emergency procedures, and make certain in discussions with the appropriate persons that these procedures, when necessary, can be made immediately operational. Interview employees to determine whether individual responsibilities are known.

IV. PHYSICAL THERAPY SERVICES (42 CFR 405.1718)

A. General.--The physical therapy services provided should be such that patients accepted for treatment are able to receive services medically indicated. The personnel and equipment necessary to effectively treat those patients will, in part, be dictated by the type of patients ordinarily accepted for treatment.

B. Major Sources of Information

- o Physician orders, plans of care, and physical therapy evaluations and progress notes
- o Patient care policies
- o Personnel records--job descriptions, employee qualifications, and current licensure information
- o Clinical records

C. Standards

Standards (a) and (b): Adequate Program; Facilities and Equipment.--Review the organization's patient care policies and clinical records to ascertain the adequacy of the physical therapy program. Compare the type of equipment available with the types of patients treated to determine whether the organization can provide the range of services required. Patients are not to be accepted for treatment unless appropriate equipment is available. Physical therapy services are to be rendered only by qualified physical therapists or qualified physical therapist assistants under the supervision of qualified physical therapists.

The physical therapist must be present: for the initiation of patient treatment for newly admitted patients or for those previously treated, discharged, and readmitted; prior to the provision of physical therapy services where a change in the physician's plan of care necessitates a change in treatment; and immediately prior to the discontinuing of treatment and discharge of patients. An evaluation or reevaluation of a patient's needs, performed by a qualified physical therapist, should precede initial treatment or treatment altered by a change in the plan of care. The physical therapist should be readily available (i.e., physically accessible to organization personnel and patients within a certain response time) to offer continuing onsite supervision regardless of whether patients are treated on the premises of the organization or in their homes. Such supervision may include specific instructions regarding the treatment regimen, an explanation of responses to treatment indicative of adverse patient reactions, and discussions between the physical therapist and the physical therapist assistant. Onsite supervision is the responsibility of the physical therapist. Response time is based on the condition of the patient, previous patient reaction to treatment, organization staffing, and competency of available personnel. For example, where previous patient reaction to treatment had been adverse, thereby possibly requiring that, in the future, the physical therapist keep himself readily available to provide needed supervisory assistance, the physical

therapist should arrange times and schedules to allow for minimal delay in providing such assistance. Additionally, when services are provided off the premises of the organization, an onsite supervisory visit at least once every 30 days is to be made by the physical therapist during the time that services are actually being furnished, in order to evaluate the quality of the assistant's performance. Review the personnel records to ascertain whether the physical therapist(s), and physical therapist assistant(s) where applicable, meet the qualifications stated in 405.1702(d) and (e).

Following are guidelines to assist in evaluating equipment commonly used in the provision of physical therapy services. Of course, an organization may meet this condition without having all the equipment referred to below.

1. Ultraviolet Equipment (UV Lamps Using Mercury Vapor Tubes)

   o Safety goggles present for patients and therapists

   o Evidence of periodic testing of lamps to determine minimal erythemal dose

   o Suitable room for ultraviolet treatment (light not visible so that effects of the inverse square law may be taken into account)

   o Suitable measuring device (tape, ruler, yardstick) available so that effects of the inverse square law may be taken into account

2. Diathermy Equipment (High Frequency Radio Wave Generators)

   a. Shortwave.--Meets Federal Communications Commission requirements; applicators in good condition

   b. Microwave.--Meets Federal Communications Commission requirements; applicators in good condition; suitable measuring device available

3. Ultrasound Generators.--Meets Federal Communications Commission requirements; applicators in good condition

4. Electrical Muscle Stimulators and Testing Equipment.--In good condition; appropriate amperage and voltage limitations

5. Hydrotherapy Equipment

   o Separate area

   o Tanks clean, in good condition; electrical equipment properly grounded

   o Cranes, lifts, and frames used in conjunction with hydrotherapy equipment in good condition

6. Exercise Equipment

- o Weight boots and bars are equipped with safe clamping collars and straps
- o Therapeutic exercise tables in good condition with special attention given to cable rigging and pulleys
- o Overhead pulleys, shoulder wheels, and stall bars are sturdy and mounted securely
- o Exercise mats are clean and in good condition; provisions are made for altering body contact surface to maintain cleanliness
- o Sand and shot bags in good condition; no tears or leaks
- o An adequate range of weight sizes or other means for varying the load applied to patients

7. Cervical and Other Traction Devices.--In good condition with safety devices operative

8. Hot Packs.--In good condition with no tears or leaks; heating units have functional thermostats that provide acceptable temperature limits and units are properly grounded

9. Paraffin Baths.--Paraffin clean and odor free; thermometer available for temperature check prior to use; heater in good condition and properly grounded

10. Tilt Tables.-- Properly grounded if electrically operated; mechanically in good condition

Where patient privacy is required, this may be accomplished through utilization of individual treatment booths, folding screens, draw curtains, etc.

Standard (c): Personnel Qualified to Provide Physical Therapy Services.--The number of qualified physical therapists and qualified physical therapist assistants (if applicable) should be able to adequately and effectively provide services to patients. Adequate service cannot be determined by the mere proportion of staff to patients. It is to be based on knowledge of the types of patients treated and the type, amount, frequency, and duration of treatment required. To more accurately determine the sufficiency of personnel, review clinical records, together with the patient care policies, personnel records and patient treatment schedules.

Standard (d): Supportive Personnel.--Physical therapy aides or individuals with less than assistant level qualifications must be directly supervised by a qualified physical therapist. The physical therapist must be on the premises and immediately available to provide assistance and direction throughout the time services are provided.

Even if an aide is assisting a qualified physical therapy assistant in some activity, ultimate responsibility for the aide's activities rests with the qualified physical therapist.

V. SPEECH PATHOLOGY SERVICES (42 CFR 405.1719)

A. General.--The speech pathology services provided should be such that patients accepted for treatment are able to receive services as medically indicated. The personnel and equipment necessary to effectively treat those patients may, in part, be dictated by the type of patients ordinarily accepted for treatment.

B. Major Sources of Information

- Physician orders, plans of care, and speech pathology evaluations and progress notes
- Patient care policies
- Personnel records--job descriptions, employee qualifications, and current licensure information
- Clinical records

C. Standards

Standards (a) and (b): Adequate Program; Facilities and Equipment.--Review the organization's patient care policies and clinical records to ascertain the adequacy of the speech pathology program. Space suitable for treatment must be available. When evaluation reveals a hearing disorder, the necessary treatment, either directly or through referral, must be provided the patient.

Standard (c): Personnel Qualified to Provide Speech Pathology Services.--Review personnel records to ascertain whether the speech pathologist(s) meets the qualifications as stated in 405.1702(j). Speech pathologists who meet the educational requirements, thereby making them eligible for a certificate of clinical competence in speech pathology granted by the American Speech and Hearing Association, and who are in the process of accumulating the supervised experience also necessary for certification (405.1702(j)(2)), qualify as speech pathologists.

The number of qualified speech pathologists should be adequate to effectively provide services to patients. As in the case of the physical therapist, this number is related to types of patients treated, the specifics of the plan of care, and the time required to carry out the plan.

Unlike physical therapy services where, at certain times, the application of certain modalities do not require the presence of the physical therapist, effective speech pathology treatment necessitates the continuing presence of the speech pathologist. Therefore, no formula utilizing numbers of physical therapists as a base for comparison can be used when determining whether or not the number of qualified speech pathology personnel is adequate.

VI. REHABILITATION PROGRAM (42 CFR 405.1720)

A. General.--A rehabilitation agency must provide either physical therapy or speech pathology services plus a rehabilitation program which minimally includes social or vocational adjustment services.

405.1720 requires the rehabilitation agency to provide social or vocational adjustment services to all patients in need of such services. The agency's qualified staff (405.1720(a)) must evaluate the social or vocational factors involved in a patient's rehabilitation program, counsel and advise on social or vocational problems due to the patient's injury or illness, and make appropriate referrals for required services. However, there are circumstances when the provision of these services to certain patients by the rehabilitation agency would be unnecessary or would duplicate similar services provided by other organizations. The rehabilitation agency is not required to evaluate patients nor to provide social or vocational adjustment services to patients under any of the following situations:

- The patient's file is clearly documented to indicate that the patient does not require social vocational adjustment services. The documentation must be provided by a physician, qualified psychologist, social worker, or vocational specialist.

- The patient is receiving social or vocational adjustment services as an inpatient or outpatient of another provider or supplier of services, and a written agreement or contract between the rehabilitation agency and the provider or supplier specifies that the provider or supplier is responsible for social or vocational adjustment services for all patients receiving OPT/OSP from the rehabilitation agency.

- The other provider or supplier agrees in the written contract with the rehabilitation agency to clearly mark or identify the files of patients receiving OPT/OSP who have previously been evaluated for social or vocational adjustment services. A separate evaluation by the rehabilitation agency of those patients for social or vocational adjustment services is not required.

- The OPT/OSP provider provides diagnostic or therapeutic services to individuals for whom another agency or organization has overall responsibility. For example, if speech language evaluation and therapy services are provided to students under a contract with a school system, the OSP provider is neither required to evaluate the need for, nor provide, social and vocational services since the school system is responsible for meeting the overall needs of students within its jurisdiction.

When a rehabilitation agency accepts a patient whose social or vocational status is not covered by one of the above situations, the agency's qualified staff must determine whether the patient's physical illness or injury indicates the need for social or vocational adjustment services. The patient's clinical record should indicate that this determination is based on information collected and reviewed by the qualified staff. A rehabilitation program may be provided by individuals not salaried employees, who are under contract to the rehabilitation agency.

Social or vocational adjustment services may be provided either on the premises or off the premises of the organization (e.g., in the office of the psychologist).

B. Major Sources of Information

- Contract for services under arrangement
- Personnel records - job descriptions, employee qualifications and health examinations as specified
- Clinical records
- Patient care policies

C. Standards

Standard (a): Qualifications of Staff.--All personnel providing social vocational adjustment services must meet the qualifications for psychologist (405.1702(f)), social worker (405.1702)(i)), or vocational specialist (405.1702(1)), as appropriate). A social worker must hold a bachelor's degree in social work conferred by a school of social work accredited or approved by the Council on Social Work Education and have one year's experience in a health care setting.

Standard (b): Arrangements for Social or Vocational Adjustment Services.--If an agency does not provide social or vocational adjustment services through its own employees, such services may be provided by means of written agreements with individuals or organizations. Their contracts must retain the agency's responsibility, control and supervision over the services and must contain details prescribed in 405.1720(b). These details are listed on the HCFA-1893. The appropriate professional staff of the organization

(i.e., physical therapists and/or speech pathologists) rendering services to the patient, as well as the professionals under arrangement (psychologists, social workers, vocational specialists) are responsible for developing, in conjunction with the physician, the regimen of social or vocational adjustment services to be provided to individuals requiring such services and must assume the professional and administrative responsibility for services provided under arrangements.

VII. ARRANGEMENTS FOR PHYSICAL THERAPY AND SPEECH PATHOLOGY SERVICES TO BE PERFORMED BY OTHER THAN SALARIED ORGANIZATION PERSONNEL (42 CFR 405.1721)

A. General.--Professional and administrative responsibility for the physical therapy and speech pathology services provide through an arrangement rests with the organization, even though such services may be arranged for with another provider of services.

B. Major Sources of Information

- Contract for services under arrangement
- Personnel records - job descriptions, employee qualifications and health examinations as specified
- Clinical records
- Patient care policies

C. Standard

Standard (a): Contract Provisions.--Review the written contract between the organization and the outside resources item-by-item to ensure that the applicable provisions listed under standard 405.1721(a) are included. Only the public health agency may contract for physical therapy or speech pathology services to be performed on the premises of a supplier of services, and the contract must contain all provisions listed in 405.1721(a).

Documentation, such as note in the clinical records and minutes of joint policy meetings, should verify that communication exists between the outside resource (i.e., the physical therapist where physical therapy services are rendered or the speech pathologist where speech pathology services are rendered) and staff of the organization.

Review the clinical records of those patients whose treatment is being arranged for (the location of treatment being either as specified in 405.1721(a)(8) or on the premises of suppliers as permitted in405.1721(a)(9)) to make certain that evaluations, progress notes, and other pertinent clinical material are present and that the clinical records containing applicable information for all patients are maintained on the premises of the organization, as well as on the premises of any location at which services are rendered.

Survey the premises of the supplier of services (405.1721(a)(9)(iv)) as soon as possible to determine compliance with all applicable Conditions and Standards except for 405.1716 (Administrative Management) and 42 CFR 405.1720 (Rehabilitation Program) and either 405.1718 (Physical Therapy) or 405.1719 (Speech Pathology), depending upon which service is not rendered by the supplier.

The appropriate public health agency professional, physical therapist or speech pathologist respectively, must, at least every 2 weeks, review the records of patients receiving physical therapy or speech pathology services on the premised of the supplier of services (405.1721(a)(9)(v)).

VIII. CLINICAL RECORDS (42 CFR 405.1722)

A. General.--The clinical record serves as a basis for documentation of medical care rendered to the patient and for communication between the physician and the personnel providing services. The surveyor determines whether the content of the clinical record presents a total or, at a minimum, an adequate picture of the care being given.

In addition to serving as a basis for documentation of care rendered to patients, clinical records provide evidence of the organization's implementation of policies and procedures as they relate to patient care.

B. Major Sources of Information

- Active and closed clinical records
- Policies regarding retention and confidentiality of clinical records

C. Standards

Standards (a): Protection of Clinical Record Information.--Clinical records are to be stored where they are protected from fire and unauthorized use. Organization policies are to note to whom records or copies thereof may be provided, the use to which the material may be put, and the circumstances describing the return of such material. For the release of all material not authorized by law, the patient's written consent is required.

Standard (b) and (c): Content; Completion of Records and Centralization of Reports.--Examine a substantial number of both active and closed clinical records, selected on a random basis and not restricted to those of Medicare patients only, to ascertain whether the appropriate material as specified in 405.1722(b) is included. The assessment of the needs of the patient (initial evaluation and reevaluations where appropriate), plan of care (including the types, amount, duration and frequency of services provided), identification data

(name and address of patient), observations and progress notes, reports of treatments and clinical findings, and discharge summary should be contained in virtually all clinical records. (Information relative to 42 CFR 405.1717(a), (b) and (c) is not applicable for non-Medicare patients receiving speech pathology services.) However, consent forms, medical history and report of the physician's physical examination may or may not appear in clinical records. This information would need to appear only where relevancy to patient treatment is shown. Where medical history does appear in clinical records, it may not have been that transmitted by the physician but, rather, may have been obtained from the patient when the past and present history was related.

If omission of any pertinent information is noted in the clinical records, additional clinical record reviews should be undertaken to determine the prevalence of such omissions. The survey should state on the Survey Report Form the number of clinical records reviewed and the number and types of deficiencies found in each. Where record reviews prompt questions concerning patient care, the surveyor should request additional information and assistance from the appropriate organization personnel.

Where emergency care is provided, the clinical record should include the following: type of care rendered, date, personnel involved, and the incident which precipitated the need for such care.

A discharge summary should include the date and reason for discharge; a brief summary of the current status of the patient at the time of discharge; and, where applicable, provision for referral of the patient to another source for continuing care. Progress notes should appear in the patient's clinical record for approximately each 2-week period.

Regardless of whether the organization provides services through its own employees or through an arrangement with others, all materials which are pertinent to the patient's treatment are to be part of the clinical record, which is to be maintained on the premises of the organization as well as on the premises of any location at which services are rendered.

All information appearing in the clinical record is to be dated appropriately, signed and incorporated within two weeks.

> Standard (d): Retention and Preservation.--The surveyor reviews the organization policy pertaining to retention and preservation of clinical records and verifies that such policy is consistent with applicable State law or regulation where such exists. There is also to be a provision in organization policies for the retention and transfer of clinical records if, in the latter instance, the organization ceases to function.

Standard (e): Indexes.--Clinical records are normally indexed according to the last name of each patient, but in some cases indexing may be according to file identification numbers assigned to patients on admission to the organization. This system may be utilized for indexing either active and/or discharged patient clinical records as determined by organizational need.

Standard (f): Location and Facilities.--The clinical records are to be easily retrievable and available to all professional staff members of the organization and other authorized individuals.

IX. PHYSICAL ENVIRONMENT (42 CFR 405.1723)

A. General.--In order to ensure the safety of patients, personnel, and the public, the surveyor examines the physical plant of the organization and ascertains whether or not it is maintained consistent with State and local building, fire and safety codes. The structure housing the organization is such that it is held "open to the public" and patient treatment areas and other locations associated with organization function (e.g., storage and toilet rooms) are to be physically separated from nonorganization areas.

B. Major Sources of Information

1. Applicable Federal, State, and local laws

2. Inspection reports of State and local building and fire authorities

3. Organization policies regarding maintenance of equipment, building and grounds

C. Standards

Standard (a): Safety of Patients.--The surveyor verifies that applicable State and local building, fire and safety codes are met, and reviews available reports of State and local personnel responsible for enforcement of the above. Areas considered to be especially hazardous (e.g., rooms or spaces used for combustible supplies and equipment) are to be equipped with a State fire authority approved automatic fire extinguishing system, or shall be separated from the balance of the building by one-hour fire resistance barriers. All areas occupied or accessible to the organization for use during emergency or nonemergency activity, including corridors and stairwells, are to be protected by easily accessible fire extinguishers (e.g., the case of an organization being located in a multilevel structure whether the entire structure is

utilized or only a portion thereof). The width of the doorways and passageways shall be such as to allow for ease in patient movement into and within the organization and may depend upon factors such as type and condition of patients accepted for treatment.

An emergency power source (e.g., battery or auxiliary generator) is available to assure adequate lighting during emergency operation within the treatment areas or those passageways, stairwells and exits (as noted above) accessible to the organization. In cases of power outage, the emergency power source should respond either automatically or require only minimal activation effort.

The fire alarm system should be adequate to alert organizational personnel in time for safe evacuation of the building. The premises of the organization are to be safeguarded by a fire alarm system or automatic detection system which is to be in operational condition. Provision is also to be made for an internally audible manual alarm capability, either separately contained, or functioning in combination with the fire alarm or automatic detection system. In the absence of State or local requirements, the above systems are to be approved by the State fire marshal's office. A system without the capacity for manual activation in response to a fire would not serve to alert other personnel, patients, and the public of danger and the need for action. Where the alarm system is activated by a disruption in the organization's electrical system or is in other ways dependent on it, an emergency power source (e.g., battery or auxiliary generator) should be available to serve as backup.

The building housing the organization should be free of hazardous occupancies or activities such as the manufacturing of combustible materials.

Standard (b): Maintenance of Equipment, Building, and Grounds.--Hazards to the health and safety of patients, personnel, and the public (e.g., broken window and door panes, obstruction of passageways, and dangerous floor surfaces) are to be noted on the Survey Report Form (HCFA-1893). All equipment should be inspected by the organization at least yearly. Such inspection is determined in part by present equipment condition and its frequency of use, and is to be outlined in written procedures which include the following: equipment to be inspected, a brief statement concerning the general inspection process, and frequency of inspection for each piece of equipment.

For all electrically powered patient care equipment, appropriate manufacturer's operating and maintenance information should be on file. The surveyor should review this information and ascertain what specific recommendations, if any, are made for equipment calibration checks, periodic maintenance procedures, etc. Then, through copies of service repair statements or other documentation, determine whether such recommendations were followed.

Written procedures covering disinfection and cleanliness of certain physical therapy equipment such as whirlpools, paraffin baths, and moist hot pack units, etc., should be available for review. This is particularly important in cases where whirlpools are used for debridement of wounds.

Standard (c): Other Environmental Considerations.--The surveyor should verify that temperature control mechanisms maintain the temperature at a comfortable and constant level. Where mechanical means of ventilation such as air conditioners are utilized, placement of the unit(s) and vents should be such that the air is dispersed uniformly throughout the facility.

Where necessary, ramps are available to provide for easy access to facilities and equipment. Examination and treatment areas are large enough to enable effective application of the plan of care. Patient privacy may be assured through utilization of individual treatment booths, folding screens, draw curtains, etc. Where underwater exercise is utilized, a safe and effective patient lift device is available.

X. INFECTION CONTROL (42 CFR 405.1724)

A. General.--An infection control committee, applicable for organizations offering physical therapy services has overall responsibility for ensuring that environmental infection hazards are controlled.

B. Major Sources of Information

1. Written policies and procedures which correspond to standards (a) through (e)

2. Minutes of the infection control committee

C. Standards

Standard (a): Infection Control Committee.--The surveyor should review the policies and procedures for preventing, controlling, and investigating infections and should ascertain whether the recommendations of the committee are acted upon. Meetings are to be held at least yearly with minutes being kept, and at least two or more individuals should constitute the committee. The committee should be composed of persons whose educational background and experience (e.g., M.D., R.N., and other interested professionals) is adequate to perform this function. The administrator, in the case of a clinic or rehabilitation agency, should assume responsibility for selecting the professionals to serve on the committee.

Standard (b): Aseptic and Isolation Techniques.--Review the aseptic procedures developed and ascertain, through a discussion with available professional personnel and review of major sources of information, that the procedures are communicated to the staff. Review the organization's documentation of its aseptic procedures.

Standard (c): Housekeeping.--The organization identifies the individual(s) assigned primary responsibility for housekeeping duties. When there is a contract with an outside resource to provide such services, the organization retains responsibility for the housekeeping duties. Survey or inspection should serve to verify the cleanliness and orderliness of the premises.

Standard (d): Linen.--A supply of fresh linen consisting of one complete set (sheet, towel, pillow case) for each patient treated, plus an additional supply to provide for increased usage, is to be stored in clean areas and available for daily use. Verify that soiled linen is removed from patient areas at least daily and stored in an area away from patients, personnel, and the public.

Standard (e): Pest Control.--Review the written policy covering the pest control program.

XI. DISASTER PREPAREDNESS (42 CFR 405.1725)

A. General.--A well developed disaster plan must be documented and posted in areas accessible for continuing personnel review.

B. Major Sources of Information

- Disaster plan
- Documentation as to ongoing training sessions and dates of disaster drills

C. Standards

Standard (a): Disaster Plan.--Ensure that the plan contains procedures to be followed, evacuation routes and assignment of responsibilities to staff. Verify that the description of the location of the alarms systems is accurate.

Standard (b): Staff Training and Drills.--Discuss with employees their specific roles in an emergency. Verify that disaster drills are carried out at least annually, and that the date and the names of those persons taking part are documented. All personnel are to be exposed to drill situations which call for the exercising of their disaster responsibilities as stated in the disaster plan.

XII. PROGRAM EVALUATION (42 CFR 405.1726)

A. General.--At least once a year the organization should assess the performance of its total operation. Total operation refers not only to those services provided to patients, but also to the broader concepts of overall organization administration, including, but not limited to, policies and procedures, personnel, fiscal, patient care, etc. Procedures are to be present which provide for an evaluation of the total organization program.

Review dated reports of the most recent program evaluations. These reports should contain the names of those participating in the evaluation, the results, and expected action, if indicated. The evaluation should be conducted by the professional staff of the organization and outside professionals, where appropriate. Determine whether, in the case of a clinic or rehabilitation agency, the governing body has been made aware of the findings. In the case of a public health agency, the group or individual (at the local level) delegated the responsibility of total program operation should be aware of the findings.

B. Major Sources of Information

- Written policies and procedures concerning the evaluation process
- Patient care policies
- Minutes of meetings on program evaluation

C. Standards

Standard (a): Clinical Record Review.--A substantial sample of records reviewed should be randomly selected from the active and closed files. Each service offered by the organization should be represented in the sample. In instances where a patient is receiving both physical therapy and speech pathology services, the record may be included in the sample of each service rendered. The clinical record review committee is

composed of health professionals representing those services provided by the organization. It is not necessary that those committee members be employees of the organization. Administrative personnel would ordinarily be committee participants.

Standard (b): Annual Statistical Evaluation.--The surveyor should review and compare the prior years and current statistical reports to determine that the data noted in the regulation, or data similar in character and more suited to the clinic's or agency's program evaluation purposes, is being kept. For example, the number and cost of units of service is a statistic more commonly retained and utilized by public health agencies and, therefore, may not be selected for use by other types of outpatient providers. Some organizations may find that a quarterly report, as opposed to an annual report, would prove more immediately beneficial in determining the effect of organizational policies. Correct and consistent application of policies will, to some extent, be reflected in the statistical evaluation, and, where policy has not been followed, the evaluation can serve as a guidepost for necessary change.

APPENDIX F

PHYSICAL THERAPISTS
IN
INDEPENDENT PRACTICE

INTERPRETIVE
GUIDELINES

APPENDIX F

Interpretive Guidelines

Physical Therapists in Independent Practice

Conditions of Participation

Condition I COMPLIANCE WITH FEDERAL, STATE AND LOCAL LAWS
405.1732

Condition II PHYSICIAN'S DIRECTION AND PLAN OF CARE
405.1733

Condition III PHYSICAL THERAPY SERVICES
405.1734

Condition IV COORDINATION OF SERVICES WITH OTHER ORGANIZATIONS, AGENCIES OR INDIVIDUALS
405.1735

Condition V CLINICAL RECORDS
405.1736

Condition VI PHYSICAL ENVIRONMENT
405.1737

I. COMPLIANCE WITH FEDERAL, STATE AND LOCAL LAWS (42 CFR 405.1732)

A. General.--Ensure that the physical therapist in independent practice and staff, if any, are licensed as required by Federal, State, and local laws.

B. Major Sources of Information

- Federal, State, and local laws governing health care, building, fire and safety codes.
- Current licensure information on the facility and on all personnel as required by Federal, State, and local laws.

C. Standards

Standard (a): Licensure of Facility.--Where State law provides for the licensing of the facility (office) of a physical therapist, verify at the time of the survey that the license is current and in effect. If such license is not current and in effect, contact the appropriate SA to determine the status of the facility's license. If no new license is to be issued, or if the facility is out of compliance with State licensure requirements, mark the standard, as well as the Condition, "not met." Under these circumstances, a physical therapist cannot be certified as an independent practitioner under the Medicare program. Attach documentation of this to the Survey Report, HCFA-3042, which becomes part of the permanent file.

Where the State indicates the licensure is provisional, document the reason(s) for such status, most importantly, any limitations imposed on the services rendered and the length of time the provisional licensure is to be in effect.

If the provisional license, or the reasons therefore, adversely affect the ability to render services consistent with regulations, mark the standard "not met" and provide a full explanation in survey report remarks or in a supplementary report as to how services are compromised.

Standard (b): Licensure of Registration of Personnel.--Current State licenses for the physical therapist and staff, where applicable, should be available for review. Verify licensure status by reviewing a central State listing or by contacting the appropriate licensing body(ies). Where you find that a valid State license is not held by a physical therapist who is currently certified for participation as a practicing independent practitioner, mark both the standard and the Condition "not met." Under these circumstances, this physical therapist cannot be certified as an independent practitioner under the Medicare program. Compliance with applicable State licensure is a prerequisite for initial eligibility and continuing coverage as a physical therapist in independent practice. Initiate appropriate State action regarding the lack of licensure of the physical therapist(s) and staff.

II. PLAN OF CARE (42 CFR 405.1733)

A. General.--All patients must be treated pursuant to a plan of care that indicates anticipated goals, and specifies the type, amount, frequency, and duration of services to be furnished. Non-Medicare patients are neither required to be under the care of a physician nor have their plan of care established by a physician.

B. Major Sources of Information.

- o Clinical records,
- o Physician orders and patient plans of care, and
- o Emergency procedures.

C. Standards

Standard (a): Medical History and Prior Treatment.--The regulations do not require that patients be referred to the therapist by a physician or that the services provided them are furnished pursuant to a physician's orders. However, since Medicare patients are required under the statute to be under the care of a physician and have the plan of care periodically reviewed by a physician to receive payment for Medicare covered services, the current medical findings, diagnosis(es), physician's orders, rehabilitation goals and contraindications would normally be made available to the therapist by the attending physician. Non-Medicare patients are not required to be under the care of a physician, have a plan of care established by a physician and have the plan of care periodically reviewed by a physician. When reviewing patients' records, if you find a referral from a physician for a non-Medicare patient, do not cite a deficiency if the referral fails to include these items. When complete and appropriate past history along with current medical findings are not made available to the organization, the organization should obtain the information either from the patient or from followup with the referring physician, if any.

The establishment of a realistic goal for each patient is dependent on the available rehabilitation potential (defined as that which would enable the patient to function at the highest level possible), which may not be apparent at the initiation of treatment. Patient evaluation provides information essential for determining the goal of treatment, and indicates the direction in which treatment will be structured. The progress made by the patient while being treated provides an indication of either an increase or a decrease in the rehabilitation potential and may require a change to be made in the plan of care.

Standard (b): Plan of Care.--When you review a patient's record to determine if a plan of care has been established and is periodically reviewed, it is not necessary to establish whether the patient is a Medicare or non-Medicare patient. The condition statement and standard permits, for each patient, the plan of care to be established by a physician, or by the physical therapist and reviewed by the individual who established it. However, as a condition for Medicare payment, a physician must review the plan of care every 30 days for each Medicare patient. This review by the physician will probably be the review the facility uses for Medicare patients to meet the Conditions for Participation.

If after patient treatment has begun, a change is required in the plan of care, it is made by a written revision and must be supported in the patient's clinical record either by documentation by the therapist, a dated written order signed by the physician, or a dated verbal order signed by the therapist receiving the order.

III. PHYSICAL THERAPY SERVICES (42 CFR 405.1734)

A. General.--The physical therapy services furnished should be such that patients ordinarily accepted for treatment are able to receive services as medically indicated.

B. Major Sources of Information

- o Written policies
- o Personnel qualifications
- o Physician orders, plans of care, physical therapy evaluations and progress notes
- o Clinical records

C. Standards

Standard (a): Adequate Program.--Therapeutic exercise equipment may consist of the following: exercise mat, parallel bars, pulley system, various types of wall mounted apparatus, and measured weights of various types and sizes. (See Appendix E, Condition IV.C. for a description of equipment.)

At least one of the modalities in each of the following groups (I, II, III) must be present in the physical therapist's office on a permanent basis:

1. Group I.--shortwave diathermy, microwave diathermy, ultrasound, moist heat pack

2. Group II.--cold pack, ice

3. Group III.--(Extremes of temperature must be able to be easily controlled and maintained.) (a) whirlpool bath, (b) contrast bath--two receptacles, the size of which should be large enough to allow immersion of an arm or leg and capable of providing temperatures of approximately 105 degrees F. in one and 60 degrees F. in the other.

Electrical neuromuscular equipment may range from that which is of some complexity, designed for ascertaining the status of the specific level of muscle and nerve function, to that utilized primarily for therapeutic muscle reeducation.

The equipment listed above is not of the scope to permit adequate treatment of a wide variety of disabilities. Therefore, in a great many situations additional equipment, as would be determined on an individual patient basis, may be required to provide adequate care. Such equipment may include a cervical or pelvic traction device, ultraviolet lamp, infrared lamp, paraffin bath, vascular compression unit, and assorted assisitive devices, to name only a few.

Possession of all equipment listed in this section is not required for compliance with Condition 405.1734; however, patients should not be accepted for treatment unless the appropriate equipment is available. In cases where a patient's condition alters, thereby requiring a change in the plan of care which may necessitate utilizing equipment unavailable in the physical therapist's office, an arrangement whereby the needed equipment is obtained through renting, leasing, etc., is acceptable.

It may become evident, through a review of clinical records of patients treated in the physical therapy office or in their homes, that in a number of cases, inappropriate equipment has been substituted for unavailable equipment which would have been appropriate. Such findings should be made by a surveyor who is a qualified physical therapist.

Standard (b): Supervision of Physical Therapy Services.--Physical therapy aides or individuals with less than assistant level qualifications must be directly supervised by a qualified physical therapist. The physical therapist must be on the premises and immediately available to provide assistance and direction throughout the time services are provided.

Even if an aide is assisting a qualified physical therapy assistant in some activity, ultimate responsibility for the aide rests with the qualified physical therapist.

The qualified physical therapist is responsible for the services provided, and for reviewing and initialing all entries made in the clinical records by other personnel.

IV. COORDINATION OF SERVICES WITH OTHER ORGANIZATIONS, AGENCIES, OR INDIVIDUALS (42 CFR 405.1735)

A. General.--The physical therapist should be responsible for providing and coordinating appropriate patient information with organizations, agencies or individuals who are also providing health services to the patient. Such coordination of information, where pertinent, is essential in order for a total program of effective care to be maintained.

B. Major Sources of Information

- o Written policies
- o Clinical records
- o Records of communication with organizations, agencies, or individuals rendering health services

C. Standard

Standard (a): Exchange of Clinical Records and Reports.--An exchange of information between the physical therapist and organizations, agencies, and individuals rendering health services to the patient must occur as often as is needed to ensure effective patient care. This should be documented in the clinical record. Documentation may take the form of minutes of meetings, reports, copies of record information, telephone reports, etc. Note via record review, specifically the areas dealing with significant past history and initial physical therapy evaluation, those patients who are currently receiving additional health services.

V. CLINICAL RECORDS (42 CFR 405.1736)

A. General.--The clinical record serves as the basis for documentation of physical therapy treatment rendered to the patient. Determine whether the content of the clinical record provides a total picture of the care being given.

B. Major Sources of Information

- o Active and closed clinical records
- o Policies regarding retention and confidentiality of clinical records

C. Standards

Standard (a): Protection of Clinical Record Information.--Clinical records are to be stored where they are protected from fire and unauthorized use. Policies are to note to whom clinical records or copies thereof may be provided, the use to which the material may by put, and the circumstances describing the return of such material. For the release of all material not authorized by law, the patient's written consent is required.

Standards (b) and (c): Content, Completion of Clinical Records and Centralization of Reports.--A substantial number of both active and closed clinical records, selected on a random basis and not restricted to those of Medicare patients only, should be examined by the surveyor to ascertain whether the appropriate material as specified in 42 CFR 405.1736(b) is included. The assessment of the needs of the patient (initial evaluation and reevaluations where appropriate), plan of care (indicating the type, amount, duration and frequency of services provided), identification data (name and address of patient), observations and progress notes, reports of treatments and clinical findings, and discharge summary should be contained in some form in virtually all clinical records. However, consent forms, medical history, and reports of the physician's physical examination may or may not appear in clinical records. This information would need to appear only where relevancy to patient treatment is shown. Where medical history does appear in clinical records, it may not have been that transmitted by the physician but rather may have been obtained from the patient when the past and present history was related. If omission of any pertinent information is noted in clinical records, additional clinical record reviews should be made to determine the prevalence of such omissions. The surveyor should state on the Survey Report Form the number of clinical records reviewed and the number and types of deficiencies found in each. Where record review prompts questions concerning patient care, the surveyor should request additional information and assistance from the physical therapist.

When emergency care is provided, the clinical record should include the following: type of care rendered, date, personnel involved, and the incident which precipitated the need for such care.

A discharge summary prepared by the physical therapist should include the date and reason for discharge; a brief summary of the current status of the patient at the time of discharge; and, where applicable, provision for referral of the patient to another source for continuing care. Progress notes should appear in the patient's clinical record for approximately each 2-week period.

All material which is pertinent to the patient's treatment is to be part of the clinical record and is to be maintained on the premises of the physical therapist's office. All information appearing in the clinical record is to be dated, appropriately signed and incorporated without undue delay.

Standard (d): Retention and Preservation.--The surveyor should review policy pertaining to retention and preservation of clinical records and verify that such policy is consistent with applicable State law or regulation where such exists. There are provisions for the retention and/or transfer of clinical records if the physical therapy practice is dissolved.

VI. PHYSICAL ENVIRONMENT (42 CFR 405.1737)

A. General.--During the survey of the physical environment, the surveyor should ascertain whether the physical therapy office complies with State and local building and fire codes, where applicable; review the procedures governing maintenance of equipment; and review the written plan for handling emergency procedures.

B. Major Sources of Information

1. Applicable Federal, State and local laws

2. Inspection reports of State and local building and fire authorities

3. Procedures for equipment maintenance

4. Emergency action procedures

C. Standards

Standard (a): Building Construction.--The surveyor should be aware of the existence of applicable State and local building and fire codes and should contact the responsible authority or review inspection reports to ascertain whether regulations have been met. In cases where an office is maintained in a home or in a residential type dwelling, the surveyor should make certain that (1) State law permits such arrangements, and (2) all applicable State and local building and fire codes are complied with.

The survey of the office should not require the services of a sanitarian if the surveyor has sufficient training to recognize whether the office of the physical therapist meets all applicable State and local building, fire and safety codes. A physical therapist surveyor with some knowledge of building and construction codes could perform the survey satisfactorily.

Standard (b): Maintenance of the Physical Therapy Office and Equipment.--Hazards to the health and safety of patients, personnel, and the public (e.g., broken window and door panes, obstruction of passageways, and dangerous floor surfaces) are to be noted on the Survey Report Form (HCFA-3042).

All equipment should be inspected by a qualified person at least yearly, and the specifics are to be outlined in writing and should include the following: equipment to be inspected, a brief statement concerning the general inspection process, person responsible for the inspection, and frequency of inspection for each piece of equipment.

For all electrically powered patient care equipment (e.g., ultrasound, shortwave diathermy, etc.), appropriate manufacturer's operating and maintenance information should be on file. The surveyor should review this information and ascertain what specific recommendations, if any, are made for equipment calibration checks, periodic maintenance procedures, etc. Then, through documentation, determine whether such recommendations, if necessary, were followed.

Standard (c): Other Environmental Considerations.--The surveyor should verify that temperature control mechanisms are maintaining the temperature at a comfortable and constant level.

Where patient privacy is required, this may be accomplished through utilization of individual treatment booths, folding screens, draw curtains, etc. Where it is required that the physical therapist utilize aseptic techniques on a continuing basis, written procedures should be in effect.

Standard (d): Emergency Procedures--Emergency procedure plans covering specific action to be taken by all personnel in attendance during nonmedical emergencies such as fire, etc., must be documented. The surveyor should review the procedures and make certain that all employees are familiar with their assigned roles.

APPENDIX G

INTERPRETIVE GUIDELINES

RURAL HEALTH CLINICS

APPENDIX G

Interpretive Guidelines - Rural Health Clinics

Conditions of Coverage

Condition I	COMPLIANCE WITH FEDERAL, STATE AND LOCAL LAWS 491.4
Condition II	LOCATION OF CLINIC 491.5
Condition III	PHYSICAL PLANT AND ENVIRONMENT 491.6
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Condition V	STAFFING AND STAFF RESPONSIBILITIES 491.8
Condition VI	PROVISION OF SERVICES 491.9
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Conditions for Certification

EXPLANATION OF CONDITIONS FOR CERTIFICATION FOR RURAL HEALTH CLINICS (RHCs)

I. COMPLIANCE WITH FEDERAL, STATE, AND LOCAL LAWS (42 CFR 491.4)

The RHC and its staff are in compliance with applicable Federal, State, and local laws and regulations.

A. Federal Laws and Regulations.--The Federal regulations governing the certification of RHCs were published in the Federal Register on July 14, 1978, 43 FR 136. Conditions for certification under those regulations are the subject of these guidelines.

B. State Laws and Regulations.--All States have practice acts that govern the activities of health professionals. While there is considerable variation in the States' practice acts concerning physician assistants, nurse practitioners and certified nurse-midwives, there is a broad mandate in the medical practice acts of all States giving physicians authority to diagnose and treat medical conditions. The extent to which the physician may delegate these responsibilities and to whom, and under what conditions, varies in the States. Some States have updated their practice acts since the advent of the physician assistant, nurse practitioner and certified nurse-midwife health care professionals. In some instances, these updated practice acts have included definitions and specific references to permitted/prohibited activities, supervision/guidance required by a physician, and location/situations in which nurse practitioners, certified nurse-midwives and physician assistants may function. In some States where nurse practice acts have not been significantly updated, some functions of the nurse practitioner are viewed as an extension of the traditional nursing role as being covered by the existing nurse practice act.

Rural health clinics can be certified only if the State permits--that is, does not explicitly prohibit--the delivery of primary health care by a nurse practitioner, certified nurse-midwife or a physician assistant. The surveyor will encounter wide variations in the wording, interpretation, and application of States' practice acts as they affect the physician assistant, nurse practitioner and certified nurse-midwife in the RHC setting.

In situations where the State law is silent, or where the State law does not specifically prohibit the functioning of a physician assistant, nurse practitioner or certified nurse-midwife with medical direction by a physician and with the degree of supervision, guidance, and consultation required by the RHC regulations, the surveyor may consider this condition as being met. Interpretations needed on specific aspects of the State's practice act should be sought through the State regulatory agency or board(s) dealing with the practice and profession.

II. LOCATION OF CLINIC (42 CFR 491.5)

Consult with the RO to preliminarily ascertain that a clinic meets the basic requirement of location prior to scheduling a survey. The clinic must be located in a rural area that is designated as a shortage area. Applicants determined not qualified under this requirement should be sent a letter (see Exhibit 27) with the appropriate notation.

A. Rural Area Location.--The law requires the clinic to be located in an area "that is not an urbanized area as defined by the Bureau of the Census." The Bureau has published both a narrative definition of an urbanized area and maps displaying the land area of urbanized areas. Lists and maps of the urbanized areas are contained in the "number of inhabitants" census volume for that State (census of population series PC-80-1-A). Note that this definition is different from that of a metropolitan statistical area (MSA). The area. Contact the Bureau of the Census ROs or the HCFA ROs for a determination on whether the clinic is located in a nonurbanized area.

B. Shortage Area Designation.--After it has been ascertained that the clinic is located in a nonurbanized area, the HCFA RO will certify whether or not the clinic is located in a designated shortage area. The HCFA RO, after consulting with PHS RO staff, promptly responds in writing to the request for a determination. This information may be given by telephone as long as it is followed by a written response. This consultation explores designation:

- o As an area with a shortage of personal health services under §330(b)(3) or 1302(7) of the PHS Act;
- o As a health manpower shortage area described in §332(a)(1)(A) of the PHS Act;
- o As an area which includes a population group which the Secretary determines has a health manpower shortage under §332(a)(1)(B) of the PHS Act;
- o As a high migrant impact area described in §329(a)(5) of the PHS Act; or
- o As an area designated by the chief executive officer of the State and certified by the Secretary as an area with a shortage of personal health services.

These designations are published periodically in the Federal Register by the PHS Bureau of Health Care Delivery and Assistance. Designation under any section qualifies a RHC location. The designation process is a continuing process, with additions of newly designated areas and deletions of previously designated areas occurring daily.

C. Mobile Units.--The Conditions for Certification must be met by a mobile unit for it to qualify as a RHC. In addition, it should be ascertained that the mobile unit has fixed scheduled locations, each of which meet the rural and shortage area requirements.

Since the mobile unit is a clinic, it is expected that the RHC services are provided in the unit and not in a permanent structure, with the unit serving only as a mobile repository for the equipment, supplies, and records. The only exception would be if the RHC services are furnished off the clinic's premises (away from the unit) to homebound patients.

Where a facility offers RHC services at a permanent structure as well as in a mobile unit, each facility must be certified separately as a RHC. This is differentiated from the situation where a permanent structure provides RHC services off the premises, e.g., to homebound patients, with the use of a vehicle to transport supplies, equipment, records, and staff.

D. Exceptions to the Location Requirement.--There are two grandfather provisions applicable to the certification process.

1. Loss of Location Eligibility.--This grandfather provision applies to the annual recertification process. It should be used as a "yes" response to item J11 and on the HCFA-30 when a facility which was previously certified as being located in a nonurbanized and designated shortage area subsequently loses either or both of these characteristics. When this occurs, the facility does not lose its eligibility for continued participation in the program because it does not meet the location requirement. If J11 is marked yes, mark J17 and J18 N/A.

2. Clinics Operating on July 1, 1977.--Potential applicants under this grandfather provision still have to meet the rural location requirement. The other requirement under this provision is that the Secretary has determined that the area served has an insufficient supply of primary care physicians. Facilities providing services on July 1, 1977, in a nonurbanized area which is determined to have unmet needs for primary health care but which is not a designated shortage area are potential applicants. Therefore, the facility may be primarily serving a designated area but not located in a designated shortage area. It must be determined whether the location of the clinic is an appropriate part of a service area which includes areas or populations which have been designated either as having a health manpower shortage, or as being medically underserved. Aiding this determination will be previous PHS decisions made on behalf of the Secretary. The answer to question V on HCFA-29 is an important indicator. Several PHS programs provide or have provided grant support to enable the facility to provide health care to designated areas. These programs do not require that the facility be located in a designated shortage area. Many of these facilities were operating with PHS grant support prior to enactment of the Rural Health Clinic Services Act of 1977 (P.L. 95-210) and may constitute certifiable RHC applicants. Some examples of these PHS programs are National Health Service Corps (NHSC), Migrant Health, Health Underserved Rural Areas (HURA), and Rural Health Initiative (RHI).

Prior to P.L. 95-210, a number of States had programs to assist their rural areas with greater access to primary care. The location of the facilities developed by these programs was determined by valid criteria established by the State, although location in a designated shortage area may not have been one of them. These facilities are also potential applicants under this grandfather provision.

When it is determined that an applicant clinic not located in a designated shortage area may be a potential applicant under this grandfather provision, develop the following information and submit it to the HCFA RO for a determination as to whether the facility meets the requirements of this grandfather provision:

- A description of the geographic boundaries of the facility's service area;

o Information developed through consultation with the PHS RO staff about whether the area, or any portion of the area, had ever been reviewed for designation under any of the applicable sections of the PHS Act;

o Identification of any designated population group or institution in the facility's service area;

o Information secured from the appropriate Health Systems Agency and the State Health Planning and Development Agency about the primary care resources available in the facility's service area;

o Information about any planning, developmental, or operating funds awarded to the facility by the county, State, or Federal Government to assist in providing greater access to health care in the area;

o Information about the factors considered in determining where the facility was to be located; and

o Any additional information the SA or RO feels is relevant.

III. PHYSICAL PLANT AND ENVIRONMENT (42 CFR 491.6)

A. Physical Plant Safety.--To insure the safety of patients, personnel, and the public, the physical plant should be maintained consistent with appropriate State and local building, fire, and safety codes. Reports prepared by State and local personnel responsible for insuring that the appropriate codes are met should be available for review. Determine whether the clinic has safe access and is free from hazards that may affect the safety of patients, personnel, and the public.

B. Preventive Maintenance.--A program of preventive maintenance should be followed by the clinic. This includes inspection of all clinic equipment at least yearly, or as the type, use, and condition of equipment dictates; the safe storage of drugs and biologicals (see 42 CFR 491.6(b)(2)) and inspection of the facility to assure that services are rendered in a clean and orderly environment. Inspection schedules and reports should be available for review by the surveyor.

C. Non-medical Emergencies.--Review written documentation and interview clinic personnel to determine what instructions for non-medical emergency procedures have been provided and whether clinic personnel are familiar with appropriate procedures. Non-medical emergency procedures may not necessarily be the same for each clinic.

IV. ORGANIZATIONAL STRUCTURE (42 CFR 491.7)

A. Basic Requirements.--Ascertain that the clinic is under the medical direction of a physician(s), has a staff that meets the requirements of §491.8, and has adequate written material covering organization policies, including lines of authority and responsibilities.

B. Written Policies.--Written policies should consist of both administrative and patient care policies. Patient care policies are discussed under 42 CFR 491.9(b). In addition to including lines of authority and responsibilities, administrative policies may cover topics such as personnel, fiscal, purchasing, and maintenance of building and equipment. Topics covered by written policies may have been influenced by requirements of the founders of the clinic, as well as agencies that have participated in supporting the clinic's operation.

C. Disclosure of Names and Addresses.--The clinic discloses names and addresses of the owner, person responsible for directing the clinic's operation, and physician(s) responsible for medical direction.

Any entity may organize itself as an owner of a RHC. The types of organizations being referred to are described in answers to question IV on the Request to Establish Eligibility. These range from:

o A physician in a private general practice located in a shortage area who employs either a nurse practitioner, certified nurse-midwife or a physician assistant;

o A nurse practitioner, certified nurse-midwife or a physician assistant in solo practice in a shortage area who develops the required relationship with a physician for medical direction; to

o Organizations either for profit or not for profit who own primary care clinics located in shortage areas.

Any change in ownership or physician(s) responsible for the clinic's medical direction requires prompt notice to the RO. Neither of these changes requires resurvey or recertification if the change can otherwise be adequately verified. Notice of any change in the physician(s) responsible for providing the clinic's medical direction should include evidence that the physician(s) is licensed to practice in the State.

V. STAFFING AND STAFF RESPONSIBILITIES (42 CFR 491.8)

A. Sufficient Staffing.--The staffing described in 42 CFR 491.8(a) is the minimum staffing requirement. However, you also determine whether the clinic is sufficiently staffed to provide services essential to its operation. Because clinics are located in areas that have been designated as having shortages of health manpower or personnel health services, they frequently are not able to employ what would be considered sufficient health care staffs. When item J42 on the SRF is marked no, explain, with reasonable detail, the circumstances (and efforts to overcome them) that make employment of additional needed staff not possible.

Should the loss of a physician, physician assistant, certified nurse-midwife or nurse practitioner member of the staff reduce the clinic's staff below the required minimum, the clinic should be afforded a reasonable time to comply with the staffing requirement. The clinic must provide some type of documentation showing the its good faith effort to obtain staff. The clinic should inform the State of all actions taken to recruit a replacement and expected outcome. The loss of a physician assistant or nurse practitioner staff member may require a temporary adjustment of the clinic's operating hours or services and an adjustment in the scheduled visits by the physician(s)

providing medical direction. The loss of the physician member will require the clinic to make temporary arrangements for medical direction with another physician(s), and this might alter the scheduled times the physician is present in the clinic. Follow these situations closely and make recommendations about approvals pending correction of deficiencies, compliance, or decertification. It is the responsibility of the clinic to promptly advise you of any changes in staffing which would affect its certification status.

B. Staffing Availability.--A physician, nurse practitioner, certified nurse-midwife (meeting the definition in 42 CFR 405.2401(b)(10)) or physician assistant must be available to furnish patient care services at all times the clinic operates. Only the scheduled operating hours the clinic is offering RHC services are to be considered (as distinguished from other ambulatory services or related health activities).

A nurse practitioner, certified nurse-midwife or physician assistant must be available to furnish patient care services at least 50 percent of the scheduled operating hours during which RHC services are offered, even though a physician is present in the clinic on a full-time basis during the time RHC services are offered. The phrase "available to furnish patient care services" means (1) providing RHC services in the clinic; (2) being physically present in the clinic even though not providing RHC services; or (3) providing RHC services to clinic patients outside the clinic. These services must be RHC services. Items (1) and (2) indicate that a physician, physician assistant, certified nurse-midwife or nurse practitioner is present on the premises, not on call, during the scheduled operating hours when RHC services are offered at the facility. Item (3) refers to that part of the clinic's operating schedule utilized in providing RHC services outside the clinic.

A RHC's total operating schedule, therefore, consists of offering RHC services at the clinic, as well as providing RHC services to patients outside the clinic. Determinants of how a clinic schedules its operating time include the size of the required staff, patient population, and where the services need to be provided. Some clinics, within their scheduled hours, may be able to concurrently offer RHC services both on and off the clinic's premises, whereas other clinics may have to schedule separate hours for offering the services on and off the clinic's premises (e.g., a clinic's total operating schedule may be from 9 a.m. to 5 p.m. daily, with on-premises services offered from 9 a.m. to 3 p.m., and off-premises services offered from 3 p.m. to 5 p.m.).

Section 1861(aa)(2)(J) of the Act requires that a physician assistant, certified nurse-midwife or nurse practitioner must be available to provide patient care services during at least 50 percent of the RHC's total operating schedule. Therefore, a physician must provide needed services at other times during the clinic's scheduled operating hours. A RHC which does not have a physician, physician assistant, certified nurse-midwife or nurse practitioner on the premises to render services during the scheduled operating hours of the clinic does not meet the requirements of §1861(aa)(2) of the Act, even though the 50 percent requirement may be met.

The following are examples of how determinations regarding these requirements may be made. A clinic has a total operating schedule of from 9 to 5 Monday through Friday, and from 9 to 1 on Saturday (44 hours a week). RHC services are offered from 10 to 5 Tuesday through Friday (28 hours a week, which satisfies the 51 percent requirement). A physician, nurse practitioner, certified nurse-midwife, or a physician assistant must be available to furnish patient care services from 10 to 5 Tuesday through Friday (28 hours a week). Of these 28 hours, a nurse practitioner, certified nurse-midwife or physician assistant must be available at least 14 hours (50 percent of 28 hours) to furnish patient care services.

In some cases, the clinic's weekly schedule may not be a logical period of time on which to base these determinations, and consideration of the biweekly or even a monthly schedule may be more appropriate. Such a situation may occur when a clinic has a very limited total operating schedule and the schedule offering RHC services is concentrated in a specified period of the biweekly or monthly total schedule. An example would be a clinic that is open only every other Tuesday and Friday from 10 to 4 (24 hours a month), and RHC services are offered every other Tuesday from 10 to 4, and one Friday a month from 10 to 4 (18 hours a month). In this situation, it is appropriate to consider the clinic's total monthly operating schedule for determining whether RHC services are offered during at least 51 percent of the schedule. A physician, a nurse practitioner, certified nurse-midwife, or a physician assistant must be available to furnish patient care services every other Tuesday from 10 to 4, and one Friday from 10 to 4 (18 hours a month). Of these 18 hours, a nurse practitioner, certified nurse-midwife or physician assistant must be available at least 9.18 hours to furnish patient care services.

C. Staff Responsibilities.--The requirement that a physician, physician assistant, certified nurse-midwife, and/or nurse practitioner participate jointly in the development of the clinic's written policies does not require the development of new policies in the event of changes in these staff members. Nevertheless, each staff member must review, agree with, and adhere to, or propose amendments to the clinic's policies. Compliance with this requirement has a special relationship to the clinic's written patient care guidelines. There should be sufficient written documentation that this requirement is appropriately carried out. There should be some mechanism to ensure that new clinic personnel are completely familiar with these policies.

1. Physician Responsibilities.--Ascertain through written documentation, such as dates and signatures, that the physician staff member satisfactorily meets the requirement of periodically reviewing the clinic's patient records, provides medical orders, and provides medical care services to the patients.

A physician member is required to be present in the clinic for sufficient periods of time to perform the duties and responsibilities described in 42 CFR 491.8(b)(i), (ii), and (iii). The term "sufficient periods of time" requires relative evaluations. There are a number of elements to consider in weighing what would constitute a reasonable time sufficient to discharge the physician member's responsibilities. These elements include: patient case load and mix (type), number of patient care records which must be reviewed in order to establish a good overview for adherence to policies and principles of quality patient care, number of patient care records which require review and discussion of specific health problems and regimens of therapy; need for consultative time with other members of the clinic's staff; need for revision to the clinic's patient care guidelines; and need for time to provide medical care to patients. Time required to accomplish these activities will fluctuate. Thus, the "sufficient time" the physician must spend in the clinic will vary. The survey should verify the time spent in the clinic by the physician for consulting records, etc.

Extraordinary circumstances which constitute exceptions to the requirement that the physician member be present in the clinic at least once every 2 weeks for "sufficient time" to discharge the physician's responsibilities are

primarily nonrecurring circumstances beyond the control of the physician and which postpone (not cancel) the visit. These circumstances include illness, extreme weather or driving conditions of short duration, or those emergencies which occur in the physician's practice and require his presence elsewhere. When nonrecurring circumstances cause postponement of the physician's visit, they should be documented in the clinic's records.

In some instances, recurring extraordinary circumstances may constitute reasonable exception to the physician's presence requirement. This type of exception requires specific approval from the HCFA RO for certification purposes, and must be documented by the surveyor. The essential areas for consideration of this exception would include:

o The remoteness of the clinic (due to extraordinary distance and inaccessibility of the terrain) make frequent travel impossible or unreasonable;

o The remoteness of the physician member's location has already placed the physician in an extraordinary extended practice and/or designated shortage area and required visits at least once in every 2 week period to a clinic located at a great distance would severely detract from the physician's practice; or

o It is clearly established in advance that continuing conditions are known to be expected (snow, flood, bridge repair, etc.) which will make reasonable access to the clinic not possible for extended periods of time.

2. Physician Assistant, Nurse Practitioner and Certified Nurse Midwife Responsibilities.--The surveyor verifies through appropriate written documentation that the physician assistant, certified nurse-midwife and/or nurse practitioner is periodically performing the necessary responsibilities listed under J51, HCFA 30.

VI. PROVISION OF SERVICES (42 CFR 491.9)

A. Basic Requirements

l. State and Local Laws.--Know the State's position, generally, with respect to implementing the Federal RHC requirements vis-a-vis the State's Medical Practice Act, Nurse Practice Act, the Pharmacy Act, and the Comprehensive Drug Abuse Prevention and Control Act of 1970 (P.L. 91- 513) and the general scope of practice permitted for nurse practitioners, certified nurse-midwives and physician assistants.

Some States may have legal impediments because applicable practice acts prohibit nurse practitioners, certified nurse-midwives and/or physician assistants from independent acts of medical diagnosis and treatment precluding the fullest implementation of the Federal RHC requirements.

This does not necessarily preclude participation by a RHC that provides RHC services (physician-type services) furnished by nurse practitioners, certified nurse-midwives and/or physician assistants under the direct supervision (as distinguished from indirect supervision) of a physician.

Therefore, inquiries to State authorities about compliance with the Federal RHC requirements, as well as decisions concerning applicant RHCs, must be weighed against several determinations, including:

o The medical direction and supervision described in the regulations is the minimum requirement; many participating RHCs operate with greater medical direction and supervision than these minimums.

o The word "supervision" does not automatically equate with direct, over the shoulder supervision. Many States requiring physician supervision of medical acts performed by a nurse practitioner or a physician assistant have held that performances of such medical acts under written patient care guidelines developed and/or approved by a licensed physician satisfy the requirement of supervision.

2. Providing Rural Health Clinic Services.--The law describes a RHC as a facility primarily engaged in providing RHC services as defined in this subpart. Under this definition, a facility may provide services in addition to RHC services; usually, related health care services such as the "other ambulatory services" covered by Medicaid State plans. Certification as a RHC applies to the facility as a whole and the total operating schedule of the facility (the hours it is open) is considered when determining if the facility is primarily engaged in providing RHC services. If onsite observation of services provided and discussion with the staff indicate that the majority of the services provided by the clinic are primary medical care (treatment of acute or chronic medical problems which usually bring a patient to a physician's office), then the clinic may satisfy the "primarily engaged" requirement providing that RHC services are offered at least 51 percent of the total operating schedule. The time RHC services are offered may differ from the total operating schedule of the facility, but may not be less than 51 percent of this total operating schedule.

If there is a question about this condition, review a sample of patient health records covering a reasonable period of time to determine the majority of specific services actually furnished.

An example of a clinic schedule that combines RHC services and "other ambulatory services" would be a clinic in which primary medical care is offered from 9 to 4 Monday through Thursday, and dental services are offered from 9 to 4 on Friday.

B. Patient Care Polices Requirements.--Review the clinic's policies and ascertain who developed them. Where changes in clinic personnel and/or clinic administration make it impossible or not relevant to ascertain who developed the policies, it is necessary to ascertain that the current physician member(s) and the nurse practitioner, certified nurse-midwife, and/or physician assistant member(s) of the staff have an indepth knowledge of the policies and have had the opportunity to discuss them, adopt them as is, or make any agreed- to written changes in them. If a clinic's organizational structure includes a governing body, ascertain whether the governing body has ultimate authority in approving the patient care policies and, if so, when such approval was last given. While clinics frequently seek the participation of other health care

professionals in developing patient care policies (particularly the written guidelines for the medical management of health problems) the term "a group of professional personnel" is not restricted to health care professionals. In some cases, the clinic will have involved health care professionals representatives to a hospital with which the clinic has an agreement for patient referral. In any event, one member of the group of three or more may not be a member of the clinic's staff, and professions which are not directly related to health care delivery (attorneys, community planners, etc.) are potentially useful.

The requirements concerning written policies address four areas:

1. Description of Services.--A description of the services the clinic furnishes directly and those furnished through agreement or arrangement. The services furnished by the clinic should be described in a manner than informs potential patients of the types of health care available at the clinic, as well as setting the parameters of the scope of what services are furnished through referral. Such statements as the following sufficiently describe services: Taking complete medical histories, performing complete physical examinations, assessments of health status, routine lab tests, diagnosis and treatment for common acute and chronic health problems and medical conditions, immunization programs, family planning, complete dental care, emergency medical care. Statements such as "complete management of common acute and chronic health problems" standing alone, do not sufficiently describe services.

Additional services, furnished through referral, are sufficiently described in such statements as: Arrangements have been made with X hospital for clinic patients to receive the following services if required: specialized diagnostic and laboratory testing, specialized therapy, inpatient hospital care, physician services, outpatient and emergency care when clinic is not operating, referral for medical cause when clinic is operating.

2. Guidelines for Medical Management.--The clinic's written guidelines for the medical management of health problems include a description of the scope of medical acts which may be undertaken by the physician assistant, certified nurse-midwife, and/or nurse practitioner. They represent an agreement between the physician providing the clinic's medical direction and the clinic's physician assistant, certified nurse-midwife, and/or nurse practitioner on the privileges and limits of those acts of medical diagnosis and treatment which may be undertaken without direct, over the shoulder physician supervision. They describe the regimens to be followed and stipulate the conditions in the illness or health care management at which consultation or referral is required.

Acceptable guidelines may follow various formats. Some guidelines are collections of general protocols, arranged by presenting symptoms; some are statements of medical directives arranged by the various systems of the body (such as disorders of the gastrointestinal system); some are standing orders covering major categories such as health maintenance, chronic health problems, common acute self-limiting health problems, and medical emergencies.

The manner in which these guidelines describe the criteria for diagnosing and treating health conditions may also vary. Some guidelines will incorporate clinical assessment systems that include branching logic. Others may be in a more narrative format with major sections covering specific medical conditions in which such topics as the following are discussed: The definition of the condition, its etiology, its clinical features, recommended laboratory studies, differential diagnosis, treatment procedures, complications, consultation/referral required, and follow-up.

Even though approaches to describing guidelines may vary, acceptable guidelines for the medical management of health problems must include the following essential elements. They:

- o Are comprehensive enough to cover most health problems that patients usually see a physician about;
- o Describe the medical procedures available to the nurse practitioner, certified nurse-midwife, and/or physician assistant;
- o Describe the medical conditions, signs, or developments that require consultation or referral; and
- o Are compatible with applicable State laws.

A number of patient care guidelines have been published by members of the medical profession. Should a clinic choose to adopt such guidelines (or adopt them essentially with noted modifications), this would be acceptable if the guidelines include the essential elements described above.

3. Drugs and Biologicals.--Written policies cover at least the following elements:

- o Requirements dealing with the storage of drugs and biologicals in original manufacturer's containers to assure that they maintain their proper labeling and packaging;
- o Requirements dealing with outdated, deteriorated, or adulterated drugs and biologicals being stored separately so that they are not mistakenly used in patient care prior to their disposal in compliance with applicable laws;
- o Requirements dealing with storage in a space that provides proper humidity, temperature, and light to maintain the quality of drugs and biologicals;
- o Requirements for a securely constructed locked compartment for storing drugs classified under Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1970;
- o Requirements dealing with the maintenance of adequate records of receipt and distribution of controlled drugs that account for all drugs in Schedules II, III, IV, and V; with Schedule II drugs being accounted for separately;
- o Requirements that containers used to dispense drugs and biologicals to patients conform to the Poison Prevention Packaging Act of 1970;
- o Requirements dealing with the complete and legible labeling of containers used to dispense drugs and biologicals to patients;
- o Requirements concerning the availability of current drug references and antidote information; and
- o Requirements dealing with prescribing and dispensing drugs in compliance with applicable State laws.

4. Review of Policies.--The group of professional personnel, which can be the governing body acting as the group, is responsible for an annual review of patient care policies.

C. Direct Services.--The purpose of the Rural Health Clinic Services Act is primarily to make available outpatient or ambulatory care of the nature typically provided in a physician's office or outpatient clinic and the like. The regulations specify the services which must be made available by the clinic, including specified types of diagnostic examination, laboratory services, and emergency treatments.

The clinic's laboratory is to be treated as a physician's office for the purpose of licensure and meeting health and safety standards. The listed laboratory services are considered essential for the immediate diagnosis and treatment of the patient. To the extent they can be provided under State and local law, the nine services listed in J61, HCFA-30, are considered the minimum the clinic should make available through use of its own resources.

If any of these laboratory services cannot be provided at the clinic under State or local law, that laboratory service is not required for certification.
Some clinics are not able to furnish the nine services, even though they may be allowed to do so under State and local law, without involving an arrangement with a Medicare approved laboratory.

Those clinics unable to furnish all nine services directly when allowed to by State and local law should be given deficiencies. Such deficiencies should not be considered sufficiently significant to warrant termination if the clinic has an agreement or arrangement with an approved laboratory to furnish the basic laboratory service it does not furnish directly, especially if the clinic is making an effort to meet this requirement.

VII. PATIENT HEALTH RECORDS (42 CFR 491.10)

A. Records System.--The clinic is to maintain patient health records in accordance with its written policies and procedures. These records are the responsibility of a designated member of the clinic's professional staff and should be maintained for each person receiving health care services. All records should be kept at the clinic site so that they are available when patients may need unscheduled medical care.

Examine a randomly selected sample of health records to determine if appropriate information, as related in J70 of the SRF and 42 CFR 491.10(a)(3), is included. This listing is the minimum requirement for record maintenance. If deficiencies are found while reviewing the records, review additional records to determine the prevalence of these deficiencies.

Record on the SRF the number of records reviewed and deficiencies found, if any, and as questions arise concerning the records, discuss them with the person responsible for record maintenance.

B. Protection of Record Information.--The clinic must ensure the confidentiality of the patient's health records and provide safeguards against loss, destruction, or unauthorized use of record information. Ascertain that information regarding the use and removal of records from the clinic and the conditions for release of record information is in the clinic's written policies and procedures. The patient's written consent is necessary before any information not authorized by law may be released.

C. Retention of Records.--Review the clinic policy pertaining to the retention of patient health records. This policy reflects the necessity of retaining records at least 6 years from the last entry date or longer if required by State statute.

VIII. PROGRAM EVALUATION (42 CFR 491.11)

An evaluation of a clinic's total operation including the overall organization, administration, policies and procedures covering personnel, fiscal and patient care areas must be done at least annually. This evaluation may be done by the clinic, the group of professional personnel required under 42 CFR 491.9(b)(2), or through arrangement with other appropriate professionals. The surveyor clarifies for the clinic that the State survey does not constitute any part of this program evaluation.

The total evaluation does not have to be done all at once or by the same individuals. It is acceptable to do parts of it throughout the year, and it is not necessary to have all parts of the evaluation done by the same personnel. However, if the evaluation is not done all at once, no more than a year should elapse between evaluating the same parts. For example, a clinic may have its organization, administration, and personnel and fiscal policies evaluated by a health care administrator(s) at the end of each fiscal year; and its utilization of clinic services, clinic records, and health care policies evaluated 6 months later by a group of health care professionals.

If the facility has been in operation for at least a year at the time of the initial survey and has not had an evaluation of its total program, report this as a deficiency. It is incorrect to consider this requirement as not applicable (N/A) in this case.

A facility operating less than a year or in the start-up phase may not have done a program evaluation. However, the clinic should have a written plan that specifies who is to do the evaluation, when and how it is to be done, and what will be covered in the evaluation. What will be covered should be consistent with the requirements of 42 CFR 491.11. Record this information under the explanatory statements on the SRF.

Review dated reports of recent program evaluations to verify that such items are included in these evaluations. When corrective action has been recommended to the clinic, verify that such action has been taken or that there is sufficient evidence indicating the clinic has initiated corrective action.

TAB A

The following publications of the Bureau of the Census include maps displaying urbanized areas:

- Bureau of Census publication series (PC(1)A entitled "Characteristics of the Population 1970 Census." This series is consecutively numbered paperback volumes dealing with individual States. the volumes may be purchased individually, and the following index shows the volume number relating to a specific State:

Parts l-53 are bound separately; parts 54-58 are bound together in on book.

1 U.S. Summary
2 Alabama
3 Alaska
4 Arizona
5 Arkansas
6 California
7 Colorado
8 Connecticut
9 Delaware
10 District of Columbia
11 Florida
12 Georgia
13 Hawaii
14 Idaho
15 Ilinois
16 Indiana
17 Iowa
18 Kansas
19 Kentucky
20 Louisana
21 Maine
22 Maryland
23 Massachusetts
24 Michigan
25 Minnesota
26 Mississippi
27 Missouri
28 Montana
29 Nebraska
30 Nevada
31 New Hampshire
32 New Jersey
33 New Mexico
34 New York
35 North Carolina
36 North Dakota
37 Ohio
38 Oklahoma
39 Oregon
40 Pennsylvania
41 Rhode Island
42 South Carolina
43 South Dakota
44 Tennessee
45 Texas
46 Utah
47 Vermont
48 Virginia
49 Washington
50 West Virginia
51 Wisconsin
52 Wyoming
53 Puerto Rico
54 Guam
55 Virgin Islands
56 American Samoa
57 Canal Zone
58 Trust Territory of the Pacific Islands

- Bureau of the Census publication PC(S1)-106. This is a supplement to the above series. It includes the current definition of an urbanized area and displays maps of 27 additional urbanized areas that were identified under the current definition.

TAB A (Cont.)

- Bureau of the Census publication PC(Sl) -108 entitled "Population and Land Area of Urbanized Areas for the United States 1970 and 1960." This new publication lists all urbanized areas and displays the geographic boundaries of each urbanized area in shaded maps. The cost is $6.00.

These publications may be ordered from the Subscriber Services Division, Bureau of the Census, Room 1121, Building 4, Washington, D.C. 20233.

TAB B

Contacts in the Bureau of the Census Regional Offices:

Atlanta	Wayne Hall	404-881-2274
Boston	Judith Cohen	617-223-0668
Charlotte, N.C.	Lawrence McNutt	704-372-0711 ext. 438
Chicago	Thomas Moss	312-353-0980
Dallas	Valerie McFarland	214-749-2394
Denver	Jerry O'Donnell	303-234-5825
Detroit	Timothy Jones	313-226-4675
Kansas City	Kenneth Wright	816-374-4601
Los Angeles	E. J. Steinfeld	213-824-7291
New York	James Hsiung	212-264-4730
Philadelphia	David Lewis	215-597-8314
Seattle	Lyle Larson	206-442-7080

TAB C

The Bureau of the Census has determined that the boundaries of some cities are so extended that they include areas having rural populations. These cities have been identified as "extended cities" and the rural portion of them meets the definition of non-urbanized areas. The following is a listing of extended cities.

I. Boston

Maine	-	Auburn City
Massachusetts	-	Fall River city

II. New York

New York	-	Rome city
New Jersey	-	Millville city
		Ringwood borough
		Vineland city

III. Philadelphia

Pennsylvania	-	Archbald borough
Virginia	-	Chesapeake city
		Virginia Beach city

IV. Atlanta

Alabama	-	Madison town
Florida	-	Jacksonville city
		Miramar city
		West Palm Beach city
South Carolina	-	Columbia city
Tennessee	-	Memphis city
Nashville	-	Davidson city

V. Chicago

Indiana	-	Indianapolis city
Minnesota	-	Apple Valley village
		Blane city
		Cottage Grove village
		Eden Prairie village
		Inver Grove Heights village
		Lake Elmo village
		Lakeville village
		Lino Lakes village
		Maple Grove village
		Medina village
		Minnestrista village

			Savage village
			Woodbury village
	Wisconsin	-	Mequon city
			Muskego city
VI.	Dallas		
	Louisiana	-	New Orleans city
	Oklahoma	-	Broken Arrow city
			Edmond city
			Jones town
			Moore city
			Norman city
			Oklahoma City city
			Tulsa city
	Texas	-	Houston city
			League city
			Texas City city
			Euless village
VII.	Kansas City		
	Iowa	-	Davenport city
			Waterloo city
	Kansas	-	Leawood city
			Overland Park city
	Missouri	-	Kansas City city
			Lee's Summit city
			Liberty city
VIII.	Denver		
	None		
IX.	San Francisco		
	Arizona	-	Scottsdale city
	California	-	Fremont city
			Hayward city
			Palo Alto city
			Roseville city
			San Diego city
			San Jose city
			Union City city
X.	Seattle		
	None		

APPENDIX H

SURVEY PROCEDURES AND INTERPRETIVE GUIDELINES FOR END-STAGE RENAL DISEASE FACILITIES

Part I
INTRODUCTION

POLICY FOR CONDUCTING SURVEYS: INITIAL CERTIFICATIONS, RECERTIFICATIONS, AND COMPLAINTS

Section 1881(b)(1) of the Social Security Act (the Act) requires facilities to be approved to participate in the end stage renal disease (ESRD) program. The regulations at 42 CFR Part 405.2100, Subpart U, specify the Conditions that facilities must meet to achieve and maintain approval.

USE OF THE SURVEY PROCEDURES AND INTERPRETIVE GUIDELINES IN THE SURVEY PROCESS

Survey procedures and Interpretive Guidelines follow pertinent sections of the Act. These provide guidance in conducting surveys of providers and suppliers participating in the Medicare program. They clarify and/or explain the Conditions for Coverage of ESRD suppliers, and they are used in measuring compliance with Federal requirements. The purpose of the procedures and guidelines is to provide suggestions, interpretations, check lists, and other tools for you to use throughout the survey process.

This survey process represents the policy of the Health Care Financing Administration (HCFA) about relevant areas and issues that should be surveyed/reviewed under each regulation, and in some cases the methods that should be used to survey those areas and issues. The use of these protocols will promote consistency in the survey/review process. The protocols also ensure that a facility's compliance with regulations is reviewed in a thorough, efficient, and consistent manner so that at the completion of the survey, you have sufficient information to make compliance decisions.

Use the information contained in the Interpretive Guidelines when you make a determination about a supplier's compliance with requirements. However, guidelines do not replace or supersede the law or regulations, and, therefore, may not be used as the basis for a citation, although they do contain authoritative interpretations and clarification of statutory and regulatory requirements and assist you in determining an entity's compliance with requirements. The guidelines do not establish requirements that must be met by facilities participating in Medicare, nor do they require any particular course of action on the part of any health care facility. Thus, they do not impose any costs or other burdens that are not already required by the relevant laws or regulations. All mandatory requirements for facilities are set forth in relevant provisions of the Act and in regulations.

When conducting surveys in accordance with the protocols, look to the substantive requirements in the statute and the regulations to determine whether a citation of noncompliance is appropriate. Citation of a deficiency may not be based on a violation of a guideline alone; a deficiency must be based on a violation of the statute or the regulations. Carefully consider how the practices of the dialysis facility relate to the illustrations within the Survey Procedures and Interpretive Guidelines, and then compare these to the specific language and requirement of the regulation before determining that a deficiency exists. Where you observe that conditions at a dialysis facility do not meet a particular guideline, that observation is a significant indication that the applicable statutory or regulatory provision may not be met. However, in each such case you must determine whether a deficiency

based on the applicable statutory or regulatory provision is appropriate. Base your decision on facts and circumstances existing at the time and such further investigations as may be warranted.

THE SURVEY PROCEDURES

The survey procedures include three separate survey protocols: A BASIC SURVEY protocol, a SUPPLEMENTAL SURVEY protocol, and an INITIAL SURVEY protocol. Each survey protocol has a different focus and purpose.

The BASIC SURVEY protocol is used for recertification surveys, and therefore assumes that the facility is fully established with a performance history. This survey protocol is designed around survey tasks that involve observing areas and actions, interviewing patients and staff, and reviewing records and documents. All of these are focused most on patient care and outcomes. This survey protocol is a guide to assist you in determining compliance with the regulations. To amplify or verify your findings, you may expand your samples, augment your interviews, or review additional documentation. If you do not find probable Condition-level deficiencies in the BASIC SURVEY, the facility is considered to be in compliance with the Conditions for Coverage, and you should conclude the survey, citing standard-level deficiencies, if any.

The SUPPLEMENTAL SURVEY protocol is initiated when Condition-level (or suspected Condition-level) problems are noted while conducting the BASIC SURVEY. The SUPPLEMENTAL SURVEY protocol is used to identify underlying problems or structural weaknesses in the operation of the dialysis facility that has or could produce Condition-level deficiencies. The SUPPLEMENTAL SURVEY is organized around Conditions for Coverage for each respective area covered in the outcome-oriented BASIC SURVEY. The SUPPLEMENTAL SURVEY can be used in whole or in part to augment the BASIC SURVEY.

The INITIAL SURVEY protocol is used for first surveys for new ESRD suppliers. This initial protocol can also be used for facilities that are changing ownership/management or location/services. During the INITIAL SURVEY, many policies and procedures are reviewed that you will not need to review again. These policies and procedures should ensure that the facility meets the basic safety and health standards of the regulations. This survey emphasizes reviewing documents and protocols, observing the site, and interviewing staff. Because patients do not have a long history with a new facility, patient interviews are not necessarily central to the INITIAL SURVEY protocol.

For a complaint survey, use whichever components of the above-mentioned survey protocols you determine are necessary to confirm or refute the complaint allegation. If the complaint alleges problems generally or in a number of service and review areas, the complaint investigation may be incorporated into the specific task(s) of the BASIC SURVEY protocol or may be investigated independently. You can decide the scope, conduct, and duration of a complaint survey.

You can treat a relocation survey as either a recertification survey or an initial survey depending upon the circumstances. Therefore, you can use either the BASIC SURVEY protocol, augmented by the SUPPLEMENTAL SURVEY protocol, or the INITIAL SURVEY protocol.

THE INTERPRETIVE GUIDELINES

The Interpretive Guidelines are a reference. As a reference, they may be used by the surveyor or the facility to delineate facility performance expectations

and the interpretation of those expectations. Whereas the survey procedures delineate priority areas for surveys, the Interpretive Guidelines address all areas of the regulation.

The Interpretive Guidelines include three columns. The first column contains the survey tag number. The second column contains the wording of the regulation from Subpart U of the 42 CFR, §405.2000. The third column contains guidance to surveyors, including additional survey procedures and probes.

Part II
THE BASIC SURVEY PROTOCOL

THE BASIC SURVEY PROTOCOL

The BASIC SURVEY protocol is used for recertification surveys. This protocol can also be used for complaint and relocation surveys. The BASIC SURVEY protocol is patient-centered, outcome-oriented, and focused.

As a patient-centered protocol, the survey protocol is organized around interviews with selected patients. The interview probes in this survey protocol recognize that each ESRD patient is an individual with a unique combination of health factors, interests, and preferred patterns of behavior. During the interviews, determine if individual patients are attaining the level of health that each wants to attain, and, if not, what factors are contributing to the patient's sense that he/she has not attained this desired level of health. Inherent in the patient-centered survey approach is the principle that the patient is qualified to assess the quality and effectiveness of the care given at the facility. It is recognized that while this principle is true in many instances, this rule cannot be generalized to all aspects of a facility's operations or to all of its ESRD patients. As with all reported problems, verify these problems before citing deficiencies.

As an outcome-oriented protocol, the BASIC SURVEY focuses on outcomes of treatment and services, whenever possible. The survey protocol incorporates both quality outcomes as experienced by patients, such as weight control, and technical outcomes, such as the purity of the water. Structural and procedural elements that are directly related to patient outcomes are taken into account in this protocol, along with the outcome assessments.

As a focused survey, the BASIC SURVEY emphasizes those aspects of care that are considered the most important indicators of quality outcomes for patients. Elements that are important, but not considered as predictive, are included in the SUPPLEMENTAL SURVEY protocol.

THE COMPONENTS OF THE BASIC SURVEY

A BASIC SURVEY of an ESRD facility consists of the following tasks:

Task 1 Preparation Presurvey Off-site.

Task 2 Activities at the Beginning of the Survey.

Task 3 Tour for Observations.

Task 4 Survey of the Reuse Area.

Task 5 Survey of the Water Treatment Area.

Task 6 Selection of Samples for Interviews and Records

Task 7 Interviews/Observations of Patients.

Task 8 Interviews/Observations of Personnel.

Task 9 Review of Clinical Records.

Task 10 Review of the Quality Assurance/Improvement Program

Task 11 Review of Operational Logs.

Task 12 Review of Personnel Records.

Task 13 Review of Affiliations.

Task 14 Assessment of Special Situations.

Task 15 Exit Conference at the Conclusion of the Survey.

I. TASK 1-PREPARATION PRESURVEY OFF SITE

Prior to each survey, review the facility's survey and certification file and facility profiles generated by other organizations. Profiles from other organizations include, but are not limited to, profiles developed by the ESRD Networks and the National Surveillance of Dialysis-Associate Diseases Form (CDC-537) developed by the Centers for Disease Control and Prevention (CDC). This review includes the following:

A. Facility File.--Review the facility's history for any prior survey and certification issues.

o Review determinations of compliance and/or noncompliance by reading previous Federal and State (if applicable) survey results. Note patterns, number and nature of deficiencies, and plans of correction.

o Review complaint allegations. Note the frequency, significance, severity, and (if substantiated) the resolution.

o Review information from the facility file including the facility's ownership, parent company (if applicable), whether the facility is hospital administered, the type(s) of service(s) offered, and the number of dialysis stations.

B. Profile from the ESRD Network.--Review information from the ESRD Network. Facility-specific information on gross mortality rates and standardized mortality rates, patient/family or facility complaints, and issues related to Medicare certification may be shared.

C. Profile from the CDC.--Review information from the National Surveillance of Dialysis-Associated Diseases Form (CDC-53.7). This information is sent to the State agencies on an annual basis from the CDC through the regional offices (ROs). This form includes information on the prevalence of HBsAg-positive patients, the prevalence of pyrogenic reactions, reuse techniques, water treatment techniques, and the type(s) of dialyzer(s) used in the facility.

II. TASK 2-ACTIVITIES AT THE SURVEY ENTRANCE

When you arrive, present your identification, introduce the survey team, and tell a key person in the facility about the purpose of the survey and the anticipated time schedule. Explain that the survey will include observations within the facility, record reviews, and interviews with patients and staff. Advise the staff that they will have the opportunity to discuss areas and to supply additional information. This introduction should be extremely brief to allow you to observe tasks as quickly as possible.

Give the facility staff person a list of the documents that you need to review during the survey. This list should be prepared off site and you should be prepared to present it as soon as you arrive. You may want to find out about any formalized patient groups that are related to the facility. You can ask which patients have leadership roles in these groups. Then you can interview these patients individually or collectively during the survey. You should post a notice that the survey is in progress and invite patients and/or staff to talk with you if they wish.

III. TASK 3-TOUR FOR OBSERVATIONS

The purpose of the observational tour of the dialysis unit is to make initial assessments of the cleanliness and infection control practices of the facility; the safety and emergency preparedness of the facility and staff; the appropriateness of the patient treatment area; and the character of patient/staff interactions. Although these observations are grouped under the initial tour, these areas may be observed at any point in the survey.

During this initial tour, you also can make some general observations about the patients and some preliminary selections of patients for interviews. Observe the general health and appearance of the patients. Observe the logistics of the facility. Note patients who would be logistically easy to interview.

Depending upon a facility's unique schedule and your travel requirements, you may arrive during the start up of the dialysis procedure, at the initiation or ending of a patient shift, or while a treatment is being conducted. Each time presents unique opportunities to view special aspects of dialysis. During start up times, you can view equipment preparation (preparing dialysate, assembling the extracorporeal system, priming the dialyzer and extracorporeal circuit) and the pre-dialysis assessment of the patient (weighing the patient, taking the blood pressure, taking the patient's pulse, assessing heart and lung sounds, taking the patient's temperature, communicating with the patient, evaluating the vascular access). Whenever you arrive, you will be able to observe staff documentation of these actions as they occur.

When the shift starts, you can observe the staff placing a needle into a fistula access and checking reused dialyzers for patient identification. At the end of a treatment, you can observe the staff discontinuing dialysis, taking vital signs, and cleaning equipment.

During a treatment, you will note the staff monitoring patients (taking vital signs, performing safety checks, monitoring the general condition of the patient), giving medications and solutions, and monitoring equipment.

At any time, you can make some general observations about the sanitation and safety of the facility, the appropriateness of the patient treatment area, and the comfort of the patient/staff interactions.

A. Cleanliness and Infection Control.--Observe the cleanliness (V145, V380, V387) and infection control and prevention practices (V380, V388, V394, V395, V396, V397) of the facility. What evidence is there that the facility is sanitary and that it follows procedures that should lead to the prevention and control of infection?

o Note if there is blood on any surface--floors, ceilings, chairs, blankets, arms, clothing, machines. You should not see any blood spills. These always should be cleaned immediately.

o Observe evidence of people following the Universal Precautions for infection control and prevention developed by the CDC and regulated by the Occupational Safety and Health Administration (OSHA) requirements. Do the staff wear and change gloves at any time of exposure to blood and body fluids? Do the staff wear and change protective clothing (including face/eye protection) appropriately? Are the handwashing procedures appropriate? Is there evidence of the prevention of cross contamination? (V388, V394, V395).

o Observe the areas around the sinks in the facility. Are paper towel holders, soap dispensers, and trash cans placed appropriately around the sinks? Are clean supplies kept away from splash areas around sinks? (V394, V395).

o Observe if waste collection and disposal are appropriate. Determine what method the facility uses for disposal of infectious/contaminated materials. Are the waste containers for trash placed and used appropriately? Are the sharps boxes for needles placed and used appropriately? (V394, V395).

o Note if hepatitis B-infected patients are treated appropriately in an isolated area. Are appropriate measures taken to prevent cross-contamination between the isolated area and the regular patient care area? Are appropriate measures taken to prevent contamination among the patients and staff in the isolated area? (V145, V380, V388).

o Note whether the ventilation and temperature of the facility seem appropriate. Do you smell vapors from disinfectants? How does the facility determine the appropriate temperature for both patients and staff? (V392, V224, V226).

o Observe the refrigerators and other storage areas. Are medications, laboratory specimens, and food stored in separate refrigerators? Are staff food items kept out of the patient care area? Are storage areas sanitary? Are clean supplies and waste separated appropriately? (V394).

B. Safety and Emergency Preparedness.--Observe the safety and emergency preparedness of the facility. What evidence is there that the facility is safe and that the staff and patients are prepared for emergencies? (V145, V380).

o See if fire extinguisher(s) and a plan for dealing with a fire or other emergency are visible. Is there evidence that the staff participates in fire drills? Is there evidence that patients understand how to cope with fire or other emergency? (V382).

o Observe the emergency equipment in the facility. Is a fully equipped emergency tray available in the unit? (V403).

o Observe the design of the facility. Is the physical layout of the facility designed for safety and emergencies? Can all patients be observed? (V391) Is there adequate space between patient chairs to provide emergency care in the event of a drop in blood pressure, nausea, and/or vomiting? (V145), V389).

C. Patient Treatment Area Set Up.--Observe the set-up of the patient treatment area. What evidence is there that the care provided at the patient's treatment area is safe and appropriate? Focus on a few patient treatment stations. If you observe any problems, continue to observe additional patient stations. (V145, V381, V387).

o Read treatment flowsheet at the patient stations. Are vital signs recorded at the initiation and conclusion of treatment? Does the flow sheet indicate periodic safety checks? If reuse is being done in the facility, are two signatures for dialyzer identification available?

o Observe the patient and the treatment area. Are the patient's arm and hand free of blood? Are clamps available to the patient for emergency takeoff? If syringes are predrawn, are they labeled with contents and the patient's name?

D. Patient/Staff Coverage, Care and Relationships.--Observe the patient/staff coverage, care, and relationships. What evidence is there that the staff coverage and behavior are appropriate and respectful? Note staff responses to patient requests and verbal interactions between patients/staff. (V339, V430, V432).

o Observe the staff coverage. How does the facility ensure:

-- That there is sufficient staff coverage?

-- That there is at least one licensed health professional present during dialysis treatments? (V432)

-- That the health professionals have credentials and authority to institute required emergency treatment procedures, such as changing a clotted dialyzer or administering intravenous medications, physicians orders, or CPR?

-- That there is a roster of physician(s) who are available for emergencies posted at the nurses station? Are mechanisms for contacting physicians satisfactory? (V175, 176).

o Observe the care. Are staff members paying attention to the patient's reaction to treatment? Are vital signs being monitored during treatment? (V424).

o Observe the relationships. Can you observe dignity and respect in the relationships among staff and patients? (V339).

IV. TASK 4-SURVEY OF THE REUSE AREA

It is of paramount importance that the reprocessing of each dialyzer be done in an appropriate and consistent manner. This survey protocol focuses on a "flash" survey of the actual reprocessing activity as quickly as possible after the surveyor completes the observational tour. The purpose of the "flash" survey of the reuse process is to determine the actual state of the reprocessing area and the behavior of the facility personnel before the facility adjusts to your presence.

Proceed with the "flash" survey of the reprocessing area. Interview a technician responsible for reuse. Because the role of personnel is so crucial to appropriate reuse, the interview with the reuse technician is an important part of this phase. If the timing is appropriate, observe the reprocessing of dialyzers at this time. If not, observe later. While in the reuse area, determine how dialyzer performance associated with reuse is handled. Reuse may be accomplished either through chemical disinfection or heat sterilization.

A. Inspect the Reprocessing Area.--Go to the reprocessing area (V226, V227, V229, V230, V293) to observe and evaluate.

o Observe the area for clean and sanitary conditions.

o Evaluate the area for adequacy of ventilation. Vapors from reprocessing materials must be maintained below potentially toxic levels. Formaldehyde vapors should be monitored at least monthly and whenever indicated by the discomfort of the personnel (V230). Testing for air quality for any disinfectants used should be in accordance with OSHA standards (V293). Note if steps are taken to reduce exposure to toxic fumes by maintaining covers on the containers of germicides and by mixing disinfectants carefully.

o Evaluate for visible, tangible separation between storage for new dialyzers, reprocessing dialyzers, and used dialyzers awaiting reprocessing (V227).

o Observe that durable gloves, eye protection (goggles or face shield, eye-wash station), and protective clothing (impervious apron) are available and used during reprocessing (V229).

B. Inspect the Reprocessed and Stored Dialyzers.--While in the reuse area, inspect the dialyzers that have been reused and are in storage. (V237, V256, V257, V258, V259, V260, V261, V262, V264, V266).

o Observe that the external surfaces (jackets) of the reprocessed dialyzers are clean with no visible blood and no leaks or cracks (V256, V258).

o Observe that dialyzer labels (including at least the patient's name, the number of previous uses, and the date of the last reprocessing) are properly applied, legible, and complete (V237, V262).

o Determine that the blood and dialysate ports are capped with no evidence of leakage (V261).

(NOTE: Caps supplied with the disinfectant peracetic acid and hydrogen peroxide (Renalin) are vented to release under pressure.)

o Observe that the dialyzer headers are free of all but small peripheral blood clots (V243, V260).

o Observe that the dialyzers are free of visible, clotted blood, except for a few clotted fibers (V243).

o Observe that the dialyzers contain ample amounts of disinfectant and a minimal air pocket.

C. Interview(s) with Technician(s) Responsible for Reuse.--During this part of the survey, determine if the personnel involved in reprocessing have adequate training and/or experience to perform the assigned tasks. There may be many technicians who work in this area, and their backgrounds may range from no medical background to licensed practitioners. Reuse technicians generally

store/handle chemicals and perform reprocessing procedures. Repairs of automated equipment are usually done by biomedical technicians, manufacturer's representatives or other personnel who have been trained by the manufacturer. (V209, V210, V211.)

o Ask the technician to describe the reprocessing procedures for dialyzers.

o Ask the technician some general questions regarding reuse. What is the average total volume of disinfectant used for reuse each day? How long is the disinfectant stable after it is mixed? Once a dialyzer is reprocessed, how long must it remain on the shelf before being used?

o Ask the technician to describe his/her behavior if it is apparent that he/she cannot perform tasks or procedures properly. Questions you can ask include: What would you do if you ran out of disinfectant? What would you do if the concentration of disinfectant is unacceptable? What would you do if you don't have enough time for the disinfectant to sit in the dialyzer? What would you do if you don't have enough room in the storage area? What would you do if you noticed that the port caps had popped off of the reprocessed dialyzer during storage?

o Ask the technician about records. Where do you record the date of each reprocessing step? Where do you record the results of testing device performance and safety?

o Ask the technician to describe the risks and actions associated with the toxic substances used in reprocessing. What toxic substances do you work with? What protective clothing do you wear and why? What do you do in the event of a large/small spill of toxic substances? Ask the technician to show you the location of equipment used to handle a toxic spill.

o Ask the technician to describe the storage and handling of reprocessing chemicals. Where do you store the reuse chemicals? Is the temperature correct in the storage area? Where are the written procedures for the handling and safe storage of reprocessing chemicals?

o Ask the technician about environmental safety. How do you ensure that toxic vapors from disinfectants are monitored as necessary? What steps are taken if the staff complains of discomfort from vapors?

o Ask the technician about quality controls. What happens when a patient has an adverse reaction? How is the reused dialyzer investigated? If a dialyzer is investigated, where is the investigation documented?

o Ask the technician to describe the training and certification necessary for working with reprocessing.

D. Observe Reprocessing.--Observe the reprocessing of dialyzers if the timing is appropriate. Dialyzer reprocessing, with either manual or automated systems, includes cleaning, performance testing, and disinfection. If the timing of the "flash" survey does not coincide with the reprocessing of dialyzers, ask the staff at what time the patient shift changes will occur and when reprocessing will begin in the reuse area. Reprocessing must be observed before the survey is completed.

An order for observing reprocessing is as follows:

o Observe, if possible, how the disinfectant solution is made

and how proper concentrations are achieved. Ask the technician to describe the process. What procedures do you follow to ensure that the disinfectant solution is mixed thoroughly? How is the concentration of germicide tested to show that it is adequate to disinfect the dialyzer?

o Observe that the dialyzer port caps are in contact with a disinfectant for a specified time period (V295).

o Observe directly that the dialyzers and headers are rinsed with treated water (not tap water) until the effluent is clear and the dialyzer is free of visible clotted blood (V240, V241, V242, V243).

o Ask how performance tests are guaranteed with reused dialyzers? How does the facility determine that the urea and creatinine clearance and ultrafiltration rates are appropriate? The facility must assure that reused dialyzers retain their efficacy to eliminate excess fluid and to clear the blood of toxins, such as urea and creatinine. Most facilities perform an indirect measurement of function by total cell volume (TCV) measurements. Ask the technician to demonstrate the process used in this facility. Observe whether the technician is performing these tasks appropriately. Ask the technician how the efficacy of reused dialyzer is measured in the facility. Commonly used methods are clinical monitoring of patients with urea reduction rates (URR), kinetic modeling (Kt/V), or blood chemistries (V244, V245, V246, V248, V249).

o Ask how the facility verifies the membrane integrity of the dialyzers. Is pressure testing and/or leak testing done on every dialyzer to verify its membrane integrity? (V248, V249)

o Ask and observe how the facility determines how many times to refill the dialyzer with germicide in order to ensure that the effluent (final) germicide concentration in the dialyzer is within 90 percent of the intended use concentration. Ask how the facility determines the adequate volume for filling the dialyzer. Ask what procedures have been developed by the facility based upon these determinations. For manual systems, observe how the technician fills the dialyzer with germicide. You may ask the following questions: Since the dialyzer fibers are wet with other liquids when you begin to fill it with disinfectant, how do you know when the concentration of germicide in the dialyzer is adequate to disinfect the dialyzer? (V253)

o Observe that the dialyzer ports are disinfected and capped with new or disinfected caps (V295).

o Observe the cleaning of the outside of the dialyzer with a low-level disinfectant (V255).

o Observe the inspection of reprocessing materials, devices awaiting reprocessing, and reprocessed devices. The storage area should minimize deterioration, contamination, and breakage (V227).

o Ask how the facility ensures that reused dialyzers are used for the same patient. Dialyzer labeling is intended to ensure that dialyzers are used only for the same patient and also to provide information essential to reuse procedures. What system is in place to flag dialyzers of patients with similar last names to alert care givers? (V234, V235, V236, V237, V262, V266, V267)

E. Review for Dialyzer Failures.--A dialyzer failure is the unexpected failure of a dialyzer to perform safely and effectively. Such failures include inadequate clearance or inadequate ultrafiltration performance and blood or dialysate leaks. Failures include a TCV less than 80 percent of the reference

TCV and more than a few clotted blood fibers in a dialyzer. These are outcome measures that should be monitored by the facility (V245, V246, V247, V249, V276, V280, V282).

o Questions for the Medical Director may include the following: What parameters has the facility established for dialyzer failures? How are these parameters measured? How do you validate that TCV measures efficacy? How do you assess the adequacy of your dialysis treatments? How is reuse considered as part of reviewing adequacy of dialysis? How many pyrogenic episodes were there in your facility during the last year? How were they investigated?

o Questions for the reuse technician may include the following: What is the mean, median, and range of reuses? How do you know that a dialyzer has failed? How do you record dialyzer failures? To whom do you report dialyzer failures? What do you do with a dialyzer that has failed? How do you introduce a new dialyzer if one fails? What do you do if the patient comes in the next day and a new or reprocessed dialyzer isn't ready?

V. TASK 5-SURVEY OF THE WATER TREATMENT AREA

Water quality is of vital importance to a dialysis facility and to the patient. The hemodialysis patient's blood can be exposed to toxic contaminants if they are present in the water. The patient's exposure to water can be through water mixed with dialysate, water mixed with reprocessing germicides, and water flushing out dialyzers. Contamination of the water system with organic and inorganic chemicals, bacteria, and endotoxins can result in adverse patient reactions, such as hemolysis, bacteremia, pyrogenic reactions (fever, chills, nausea), or death. Some contaminants can cause chronic health defects (e.g., aluminum) and others can be fatal (e.g., fluoride).

An ESRD facility must monitor the quality of the water used in treatments and monitor the equipment used in water treatment. The Association for Advanced Medical Instrumentation (AAMI) has published guidelines for water treatment and for reprocessing dialyzers. The ESRD regulations have incorporated by reference the AAMI recommended guidelines for the reuse of hemodialyzers but not AAMI's guidelines for water treatment. The regulations require water that is biologically and chemically compatible with acceptable dialysis techniques. The reuse regulations require that the quality of water used for reprocessing must have less than 200 colony forming units of bacteria per milliliter (cfu/mL) and/or less than one nanogram of bacterial endotoxin per milliliter (ng/mL).

Your assessment of the water treatment system will consist of observations and interviews in the water treatment area at this time (V386, V216). During your review of operational records, review records of water specimen analysis and equipment maintenance (V217, V218, V252, V253, V254). Monitoring of patient blood chemistries and symptoms, part of your review of clinical records, will be another way that you will check for the effects of inadequate water treatment (V146, V338, V294).

A. Water Treatment Area and Equipment.--Inspect the water treatment equipment.

o Observe the components of the water treatment and distribution system to ensure that they are compatible and will not leach toxic elements. Copper, zinc, brass, or aluminum components should not be used in the distribution system after the first processing element in the dialysis water treatment system.

o Determine that there are no stagnant flow areas in the fluid distribution system that can't be easily sanitized. Observe that sampling ports are located after each component of the water treatment system.

o Observe how bicarbonate concentration is prepared and stored. Are the containers used in the preparation or delivery of bicarbonate concentrate rinsed and completely drained at the end of each day? Are they disinfected periodically?

B. Interview the Staff.--Interview the person responsible for water treatment. Questions to ask include, but are not limited to:

o The daily start-up procedure: Who starts the system? Who tests the water? How often do you test for chlorine/chloramines? What are the accepted limits? What do you do if you exceed those limits? Do you ever put the water treatment system in by-pass? Who determines if the system goes into by-pass? What happens to reuse if this occurs? Who does this when you are not here? Determine who is required to start the system and if they have the required information.

o The local water system: What contaminants are common in your local water? Does your local water department require a back flow preventor? How would your local water department contact you in the event of an emergency or change?

o The water analysis: How does the facility test hemodialysis fluids (i.e., water for dialysate, water for reuse, dialysate) for chemical, bacterial, endotoxin concentrations? How does the medical director document his/her review? What limits are set up by the facility? What action is taken if the chemical, bacterial, and/or endotoxin analyses reveal levels of toxins above specified limits? Where do you document corrective action for results that are not within standards?

Examine the results of water analysis. If the water microbial assay results do not seem credible (e.g., consistent reports, "no growth"), consult with the off-site laboratory doing the tests. Check on the culture medium, temperature and time of incubation, and assay procedures. If appropriate procedures are not followed, the sensitivity of the assay may not be valid.

VI. TASK 6-SELECTION OF SAMPLES FOR PATIENT INTERVIEWS, PERSONNEL INTERVIEWS, AND RECORD REVIEWS

For patient interviews and record reviews, consider the demographics of patients that the facility serves. Although it may not be possible to select a statistically valid random sample of patients, it is possible to select a cross section. Choose a variety of patient interviewees and records. Try to select patients who are normative. Factors to consider in the sample selection may be the patient's age, length of time on dialysis, site of dialysis (facility, home, skilled nursing facility), choice of modality (hemodialysis, peritoneal dialysis, pre- or post-transplant), shift and schedule, co-morbid conditions, and degree of medical, nursing, psychosocial (including psychosocial), and nutritional interventions required. Although you cannot choose specific patients until you arrive at the facility, you can determine which factors you are going to consider prior to the on-site survey.

The sampling process is important. However, it is not intended to be a statistically valid random sample. The sample of interviewees and records should be sufficient to give the surveyor enough information to make required decisions.

Generally, the core sample for patient interviews should be ten percent (10%) of the patient population, with at least 5 patients interviewed for facilities with a patient population of 50 or under, and a maximum of 15 patients in a facility with more than 150 patients. However, you may always extend the number of core sample interviews conducted or records reviewed as needed. Home patients may be interviewed by telephone.

Personnel interviews will include interviews with the person responsible for medical direction, nursing services, nutritional services, and social and rehabilitation services. If the person responsible for the specific service is not available, a designee may be interviewed. You also will be interviewing the person responsible for reuse and the person responsible for water treatment. These individuals may be interviewed early in the survey process.

VII. TASK 7-INTERVIEWS/OBSERVATIONS OF PATIENTS

This survey protocol includes interviews with selected patients. The interview should solicit information about the patient's clinical status, about the comprehensive multidisciplinary care received and the patient's satisfaction with it, and about the patient's understanding of the facility's clinical and administrative policies. Family members of patients may also be able to provide some of this information. Individual interviews should occur in private, away from other patients and staff to the greatest extent possible.

The interview questions take into account the fact that each ESRD patient is an individual with a unique combination of health factors, co-morbid conditions, goals, and preferred patterns of behavior. You will want to interview a variety of patients, realizing that some patients have very strong feelings about their disease and treatments and other patients may be very protective about their facility or staff. Some patients may be concerned about answering questions forthright in front of the staff. However, an overview of the consensus within the sample selected should provide an accurate overall portrait of the care experienced by the patients in this facility.

A. Clinical Status.--Interview the patient about his/her clinical status.

o Find out if patients are aware of their unique clinical problem areas and the behaviors related to clinical areas. Questions may include the following: What things do you need to be careful about because of your renal disease and treatment? What do you do to manage those areas of your health? (V330, V334, V339, V424)

o Elicit information about the efficacy of the dialysis treatments in general, such as: Do you feel like you need dialysis when you get on the machine? Ask about emergency dialyses for pulmonary edema, episodes of chills, problems with repair of accesses. How is your blood pressure controlled during treatment? How do you feel when you finish your treatment? Is your weight goal achieved when your treatment is finished? How are your laboratory values? Has anyone discussed "adequacy of dialysis" with you? How would you know if you have had an "adequate" dialysis treatment? Are you familiar with the terms "Kt/V" or "urea reduction ratio"? What do they mean to you? Do you have questions about your dialysis procedure that you are uncertain about? (V424)

o Find out about the patient's specific experience with the individual dialysis treatments. Do you have any concerns/problems with the needle puncture at your access site? If you experience clinical symptoms while on dialysis, such as itching, chills, fever, who do you tell? What happens? Do you feel safe? Do you feel well cared for here? Do you feel that the staff cares about you? (V423)

o Find out about the patient's general sense of well-being. How is your appetite? Are you losing real weight? How do you sleep? How do you feel when you arrive home? (V423)

B. Comprehensive Multidisciplinary Care.--Interview the patient about the extent to which he/she receives comprehensive, multidisciplinary care.

o Ask about the patient-care planning process and the long-term care program. How does the facility determine your needs? Which health care professionals participate with you in patient-care planning and long-term care planning? How often do you meet? How are you encouraged to develop short-term and long-term goals for yourself? What are your short-term and long-term goals for yourself? Has someone talked with you about your suitability for transplantation? Who? What did that person say? Where are you on a list? (V310, V317, V315)

o Find out about basic multidisciplinary roles and coverage in the facility. Who prescribes the type of dialyzer you use? Who gives you medications? Who checks your blood pressure? How frequently? Who interprets your laboratory work for you? Who helps you with your nutrition? Who talks to you about the services which are covered under Medicare? Who helps you with personal problems like adjusting to your illness, family support, or feelings of depression? Who talks to you about your rehabilitation possibilities? About rehabilitation and employment counseling? Who talks to you about exercise possibilities? (V177, V430)

o Find out about what happens off site. Do you discuss things that go wrong at home, such as bleeding from the access site, diarrhea, pain or headaches after dialysis, or depression, with the staff? Have you ever discussed these things with the staff? Were people helpful? How were they helpful? Do you receive home health care? If so, is there communication between the home health agency and the ESRD program? (V175, V176, V424, V430, V446, V448)

o Find out if care is individualized. If you wanted to know everything that you could do to be healthy, is there someone who could help you? (V430)

o Find out about the numbers of staff. Do you think that there are enough staff members present to care for you and the other patients safely? Can you describe any time when you felt that there were not enough staff members present? (V430)

C. Understanding of Facility Policies.--Interview the patient about his/her understanding of the facility's clinical and administrative policies.

o Ask the patient if he/she knows about the facility's grievance mechanism. Do you know about the facility's grievance mechanism? Do you feel comfortable with the facility and staff or are you too intimidated to express concerns? If you had a problem at the facility who would you talk with? What would you do if the problem wasn't fixed? Do you know about the network's grievance mechanism? Have you or anyone you know needed to use the grievance

mechanism? What happened? If a facility has never received a patient complaint, the grievance procedure may be too confusing or intimidating (V342).

o Ask the patient about medical emergencies and disasters. What would you do in case of a medical emergency at the facility? At home? What does the facility expect you to do in the case of a fire or other disaster? (V177, V179, V406)

IX. TASK 8-INTERVIEWS/OBSERVATIONS OF SELECTED PERSONNEL

Interviews and observations with selected personnel are an important component of this survey protocol. These interview questions are geared to elicit outcome-Oriented responses. It is recognized that staff members have important
contributions to make to the survey process. It is also recognized that individual staff members, like patients, can be influenced in his/her responses by personal feelings and relationships.

The challenge for ESRD personnel is to collectively provide treatment to patients that they want, that can maintain or improve their health and that is as error-free as possible. Caring for the ESRD patient includes offering medical, nursing, technical, nutritional, and social and rehabilitative services. Teams of caregivers make coordinated care possible. Staff members will bring different knowledge and experience to the treatment team. Collectively, the team of health-care providers should offer comprehensive, multidisciplinary care. As a surveyor, you want to determine how aggressively the facility tries to find out what their patients need and want and how they deliver it, assess it, and change it as needed. You will want to determine how they manage multiple, sometimes conflicting, priorities.

A. Role Coverage and Multidisciplinary Relationships.--Interview a person responsible for medical direction, for nursing services, for nutritional services, and for social and rehabilitative services (V420, V430, V440).

o Find out about roles. What is your job? What are the roles of others, e.g., the dietitian and the social worker? How would you expand your role if you had more time and money? What evidence is there that: the nursing needs of the patients are being met?

-- The nutritional needs of the patients are being met? that the social service needs of the patients are being met?

-- How do you measure and prescribe an "adequate" dialysis?

o Find out about interdisciplinary relationships. How do you communicate with other team members? How do you communicate with the Medical Director? What meetings do you have together? What evidence is there that the care of the patient is truly interdisciplinary?

B. Training and Supervision.--Interview nursing and technical staff about training and supervision. What training do you have to do your job? What qualifications are required for someone to do your job? Who answers questions and provides direction when you need it? How is continued proficiency demonstrated and documented on a continuing basis? How is the staff credentialed on an ongoing basis? How do you participate in quality assurance/improvement programs in the facility? How does the facility's training program relate to the quality assurance program? (V149, V154, V402)

C. Administrative Support.--Interview the staff about administrative areas. How do you feel about the staff-to-patient ratios? What do you do when someone calls in sick? How do you feel about the physical environment at your facility? What health exams do you have in relation to your job? What grievance mechanism is available for the staff? (V147, V153)

IX. TASK 9-REVIEW OF CLINICAL RECORDS

Review the records for the sample of selected patients. These patients should be interviewed, if possible. You should review the prescriptions for dialysis, the long-term programs and patient care plans, and the treatment records. You may review as many records as you find necessary to make determinations about compliance.

The facility should use documentation of the patient's treatment in a variety of ways, including as a diagnostic and communication tool for the team, as a
basis for the prescription for therapy, and as a record of and a stimulus for quality assurance activities.

A. Dialysis Prescriptions.--Review the records to determine if dialysis prescriptions are individualized. What does the facility target as a measure of adequate dialysis? Is there an individual prescription for dialysis for each patient? Is the provided treatment the same as the treatment prescribed? Are the dialyzer, blood flow rate, time, and target weight listed on the treatment provided as ordered? If the treatment does not allow attainment of the adequacy target, is an action taken such as a change of blood flow, a different size dialyzer, or a different amount of time on dialysis? Is the vascular access evaluated? (V177, V393)

B. Long Term Programs and Patient Care Plans.--Review the long-term care plans and patient care plans. How are the long term programs and patient care plans individualized for each patient? How do the care plans incorporate the records of the different disciplines? How does the care plan reflect an assessment of patient's needs? How does the care plan reflect changes in patient's needs? How does the long-term program reflect an assessment of the patient's preferences for a suitable modality (transplant, hemodialysis peritoneal dialysis) and a suitable setting (home, facility)? How does the transplant surgeon participate in the development of the long-term care program? (V310, V312, V317, V313, V314, V315, V318, V319, V321)

C. Treatment Records.--Review the patient's treatment records. How do the daily treatment records note times on/off dialysis, predialysis safety checks, vital signs-monitoring during dialysis, medication administration, and notations of adverse reactions? Do the progress notes provide an accurate picture of the progress of the patient and changes in patient status, plans, and results of changes in treatment regimen, diagnostic testing, consultations, or unusual events? Is dry weight consistently achieved? Are laboratory results documented? How do the records show that someone has reviewed, analyzed, and responded to the results of the laboratory reports? Do the nursing or medical notes show that someone responded to unexpected laboratory results? Does the record include an admission history and current physician's orders? How does the physician update the record for prescriptions and medications? Is there documentation indicating that patients have completed their consent for treatment forms and have received their rights and responsibilities' and grievance procedures' documents? (V351, V367).

X. TASK 10-REVIEW OF THE QUALITY ASSURANCE/IMPROVEMENT PROGRAM

Quality assurance (QA) in renal care covers a wide range of areas and applications. Some of these include: monitoring appropriateness and outcomes of therapy, assessing patient satisfaction, credentialing staff, measuring mortality and morbidity with the subsequent implementation of potential solutions, and monitoring of technical and clinical processes with suitable modifications when standards are not met.

The regulations define a broad quality assurance/quality control program which is required for each facility that reuses dialyzers. The regulations also address monitoring accident and incident reports in the facility. Review the quality assurance records in the facility. (V146, V388, V294)

A. Interview Staff.--Find out from the staff about the quality improvement program in the facility. How does the quality improvement program operate? How are quality improvement decisions made? What aspects of care does the facility monitor in its quality improvement program? What flags are used by the facility personnel to detect deteriorating clinical status in the patients? How are unexplained changes in serum creatinine or albumin recorded and investigated? What evidence is there that the facility has instituted a practical process for quality assurance/improvement in the facility, and not simply a program to correct problems when they are detected?

B. Review Records.--Review records and logs to ensure that the facility has a comprehensive quality assurance recordkeeping system. Where are incident and accident reports maintained? How are patient and staff complaints recorded? How are infections monitored? Where are equipment failures reported? Who reviews? How often? Do minutes of the QA committee regularly exist? Do records of formal QA activities exist? Does reuse QA comply with AAMI standards?

XI. TASK 11-REVIEW OF OPERATIONAL LOGS

Ensure that operational logs are kept and reviewed. These operational logs should include records for the dialysate delivery and blood circuit system; records for reprocessing; and record for the water treatment system and water quality. These logs may be reviewed when convenient. (V383, V222, V223, V224, V225, V386)

A. Delivery and Circulation System.--Review logs for monitoring, preventive maintenance and repair, and review of system. What logs are kept for the dialysate delivery and blood circuit system? Who reviews the logs? How often? Does the monitoring comply with manufacturer's instructions? (V383)

B. Reprocessing.--Review the reuse records for documentation regarding rinsing and cleaning, testing, and disinfecting. Does the facility have either (1) operating manuals for automated reprocessing equipment, or (2) complete process protocols developed by the facility for manual reprocessing equipment? Does the facility maintain records that can determine how each dialyzer was reprocessed? Who performed the procedure? When was the dialyzer reprocessed? Are dialyzers tested for performance? What test results are achieved? What do logs of discarded dialyzers reveal as the reasons for discard? Are these records accurately and completely maintained? (V222, V223, V224, V225)

C. Water Treatment.--Review records of water specimens analysis and equipment maintenance. What documentation does the facility have for maintenance, calibration checks, and testing of the water treatment system? What tests are done daily or prior to each patient shift? What records does the facility maintain for disinfection and for test results of disinfection? (V386)

XII. TASK 12-REVIEW OF PERSONNEL RECORDS

Review the personnel records. Record review will include a review of current licensure records, as well as health and training records for the staff. Do the staff meet applicable Federal, State, and local regulatory requirements? What is the incidence of hepatitis B conversion among the staff? What measures are taken to prevent and control the transmission of infection among staff? What orientation and in-service training is available for the staff? (V103, V144, V145, V147, V141)

XIII. TASK 13-REVIEW OF AFFILIATIONS

Note that the facility participates with outside organizations, as required and appropriate. Does the facility participate with the ESRD Network? Does the facility participate with a transplant organ registry? Are the Food and Drug Administration and manufacturers notified if patient reactions or technical problems appear to be associated with any commercially-obtained device? (V115, V455, V104)

XIV. TASK 14-ASSESSMENT OF SPECIAL SITUATIONS

Some facilities will have special situations that require special survey assessments. These special situations include responsibility for home patients, responsibility for nursing home patients, and responsibility for pediatric patients.

A. Home Patients and Nursing Home Patients.--Review the records of patients who dialyze off-site for whom the facility is responsible. Home visits may be done if in the surveyor's opinion, they are needed. Home visits may be needed if you find poor outcomes, an absence of necessary information on home patients, or complaints (V368, V449, V450, V451, V452, V453, V454).

o Review the records of home dialysis patients. How are records kept for home dialysis patients? Who reviews these records? How are social and dietary services provided to home patients?

o Review the records of nursing home patients. How are records kept for patients who dialyze in a nursing home? Who dialyzes the patient? How are the nursing home staff involved with the dialysis procedure? How are equipment emergencies handled? How are clinical emergencies handled? How is infection control handled? How is water tested and treated? Who is trained and by whom? How do ESRD and nursing home providers interact?

B. Pediatric Patient.--Review the records of pediatric patients to make sure that their special needs are acknowledged. It is especially important that the facility track the cognitive development of pediatric patients and closely monitor and respond to their unique medical, nursing, nutritional, and developmental, educational and psychosocial needs (V440).

XV. TASK 15-BEHAVIOR AT THE END OF THE SURVEY: EXIT CONFERENCE

Prior to the exit conference, come to an agreed judgement on the severity of the deficiencies and whether their number, character, and combination interfere with the delivery of adequate care, and create hazards to patients' health and safety.

The general objective of the exit conference is to communicate informally with the facility representative about your preliminary observations and findings at the end of the survey. You may either describe to the facility the requirements that you tentatively have decided are not in compliance and the

findings that substantiate the deficiencies, or you may inform the facility that requirements appear to be met based upon a preliminary analysis of the findings of the BASIC SURVEY protocol.

Although it is a general policy to conduct an exit conference, there are situations that justify your refusal to conduct or to continue an exit conference. For example, you may refuse to continue a conference if an attorney attempts to turn an exit conference into an evidentiary hearing or if a person creates an environment that is hostile, overly intimidating, or inconsistent with the informal and preliminary nature of an exit conference.

When you have completed the exit conference, tell the facility representative that a formal statement of deficiencies (if any) will be mailed. If you have identified an immediate and serious threat to patient health and safety, explain the significance of finding(s) and the need for immediate corrective action. If other deficiencies are found, explain the due date for submitting a plan of correction. Make it clear that only compliance will stop an adverse action.

In an initial survey, tell the supplier to expect notification of initial approval or denial of Medicare participation from the RO. Explain that the RO establishes the effective date of participation and notifies the supplier in writing, and that Medicare payment will not be made before the effective date.

Use The Principles of Documentation as your guide in writing your statement of deficiencies.

Part III
THE SUPPLEMENTAL SURVEY PROTOCOL

THE SUPPLEMENTAL SURVEY PROTOCOL

A SUPPLEMENTAL SURVEY protocol is initiated when Condition-level (or suspected Condition-level) problems are noted while conducting the BASIC SURVEY. The SUPPLEMENTAL SURVEY protocol is used to identify underlying problems or structural weaknesses in the operation of the dialysis facility that has or could produce Condition-level deficiencies. The SUPPLEMENTAL SURVEY is organized around Conditions for Coverage of each respective area covered in the outcome-oriented BASIC SURVEY. The SUPPLEMENTAL SURVEY can be used in whole or in part to augment the BASIC SURVEY.

Do not be constrained by the suggestions that certain Conditions be reviewed. If different Conditions apply, then exercise professional judgement in deciding to review them. View the SUPPLEMENTAL SURVEY as an extension of the BASIC SURVEY. This extension can be used in whole or in part to complete a survey.

THE COMPONENTS OF THE SUPPLEMENTAL SURVEY

Task 1 Tour for Observations.

Task 2 Survey of the Reuse Area.

Task 3 Survey of the Water Treatment Area.

Task 4 Interviews/Observations of Patients.

Task 5 Interviews/Observations of Personnel.

Task 6 Review of Clinical Records.

Task 7 Review of Quality Assurance/Improvement Records.

Task 8 Review of Operational Logs.

Task 9 Review of Personnel Records.

Task 10 Review of Affiliations.

Task 11 Assessment of Special Situations.

I. TASK 1-TOUR FOR OBSERVATIONS

A. Cleanliness and Infection Control.--If you find problems in the areas of sanitation or infection control, review the policies and procedures regarding sanitation and infection control and prevention. Consider looking further into the following Conditions for Coverage.

o Governing body and management (V111).--Review the personnel policies and procedures, the staff training, and the trainee supervision as related to sanitation and infection control. How do the policies and procedures ensure a sanitary and safe environment? How does the facility routinely test for hepatitis and other infectious diseases? How does the facility ensure that the staff are adequately trained in infection control and prevention? What supervision and oversight is provided for staff to ensure that the policies and procedures for sanitation and infection control are followed?

o Physical environment (V380).--Ascertain if the facility is equipped and maintained to provide a sanitary and safe environment for patients and staff. How are infections and infection rates in the facility monitored and reported? How does the facility ensure that universal precautions for infection control are followed? How does the facility prevent cross contamination between areas that need to be segregated? How are waste storage and disposal handled? How is the temperature and ventilation in the facility monitored?

o Medical director (V420).--Determine how the medical director provides supervision for the training of the staff and for the development and availability of a patient care policy and procedures manual and its implementation. How does the medical director ensure adequate training of the staff in sanitation and infection control? How does the medical director monitor the development, availability, and implementation of policies and procedures regarding cleanliness and infection control?

B. Safety and Emergency Preparedness.--If you find problems in the areas of safety and emergency preparedness, review the policies and procedures related to this area. Consider looking further into the following Conditions for Coverage.

o Governing body and management (V110).--Note that the governing body is responsible for the maintenance and implementation of policies and procedures that ensure a safe environment for patients and staff. How does the

governing body ensure that the facility is a safe place to dialyze and that the patients, staff, and equipment are prepared for emergencies? How does the governing body ensure that there is always available medical care for emergencies, 24 hours a day, 7 days a week?

o Physical environment (V380).--Note that the physical environment is safe for patients, staff, and the public. How does the facility ensure that fire regulations and fire management procedures are followed properly? How does the facility ensure that all electrical and other equipment is free of defects? How does the facility annually review and test the emergency procedures for fire, natural disasters, and equipment failure? How are these procedures updated and revised? How does the facility guarantee that personnel are knowledgeable and trained in their respective roles in emergency situation? How does the facility ensure the surveillance of patients for safety while they are receiving dialysis treatments?

C. Patient Treatment Area Set-Up.--If you find problems in the patient treatment set-up area, review the treatment progress notes. Consider looking further into the following Conditions for Coverage.

o Governing body and management (V110).--Note that the governing body needs to ensure that there are policies and procedures to ensure a safe and sanitary environment. How does the governing body ensure that the patient treatment area is safe and sanitary?

o Medical records (V350).--Review the medical records to ensure that the medical records are maintained in accordance with accepted professional standards and practices. How does the facility ensure that medical record entries concerning observations and treatment progress notes are appropriately documented, completed, and maintained?

o Physical environment (V380).--Observe if the physical environment at the patient treatment area is safe and functional. How is the patient treatment area set up to ensure a safe and functional environment for the dialysis treatments?

D. Patient/Staff Coverage and Relationships.--If you find problems in the coverage and relationships of patients and staff, review the staffing logs and patient/staff schedules. Consider looking further into the following Conditions for Coverage.

o Patient's rights and responsibilities (V330).--Review the policies and procedures regarding the treatment of patients. How are the facility policies and procedures operationalized to ensure that patients are treated with respect, dignity, and recognition of their individual needs?

o Staff (V430).--Review the staffing patterns. How do the staffing patterns developed by the facility guarantee that properly trained personnel are present in adequate numbers to meet the needs of the patients, including those arising from medical and nonmedical emergencies? How do the staffing patterns ensure that one currently licensed health professional experienced in rendering ESRD care is on duty whenever dialysis is in progress to oversee ESRD patient care?

II. TASK 2-SURVEY OF THE REUSE AREA

If you find problems with the reprocessing of dialyzers and other dialysis supplies, review policies and procedures on reuse. Consider looking further into the following Conditions of Coverage.

o Governing body and management (V110).--Note that the governing body needs to ensure that there are policies and procedures to ensure proper reprocessing. How does the governing body monitor reuse?

o Medical director (V420).--Is the Medical Director aware of reuse practices and procedure?

o Reuse (V200).--How does the facility comply with the standards from the AAMI recommended practice for the reuse of hemodialyzers?

III. TASK 3-SURVEY OF THE WATER TREATMENT AREA

A. Water Treatment Area and Equipment.--If you find problems in the water treatment area or with the water treatment equipment, review policies and procedures on water treatment systems and equipment maintenance. Consider looking further into the following Conditions for Coverage:

o Physical environment (V380).--How does the facility ensure that the water used for dialysis treatments is biologically and chemically
acceptable? What test results and equipment maintenance schedules are maintained?

o Reuse (V200).--How does the facility meet the water treatment standards that are a part of the Association for the Advancement of Medical Instrumentation guidelines on the Recommended Practice for the Reuse of Hemodialyzers?

B. Interview of the Person Responsible for Water Treatment.--If you find problems during your interview with the person responsible for water treatment, look further into the same Conditions for Coverage listed under Water Treatment Area and Equipment.

V. TASK 4 INTERVIEWS/OBSERVATIONS OF PATIENTS

A. Clinical Status of Patients.--If you find problems in the area of clinical care of patients, review the structure of the medical records and quality assurance systems and review the policies on the dialysis prescription. Refer to Task 6 of the Basic Survey when selecting a sample for patient interviews. Consider looking further into the following Conditions for Coverage.

o Patient's rights and responsibilities (V330).--How does the facility ensure that patients are fully informed about their medical condition and treatment? How does the facility monitor that extent to which the patient is informed? How is this documented in the patient's clinical record?

o Medical director (V420).--How does the medical director ensure that each patient receives an adequate dialysis? What standards does the medical director use to prescribe dialysis treatments? When and how does the medical director adjust an individual patient's dialysis prescription? How is the medical director alerted to clinical symptoms that a patient is having while on dialysis? Who monitors laboratory values? How/when is the medical director informed of laboratory values? How/when is the medical director notified of treatment outcomes inconsistent with those intended?

B. Comprehensive Interdisciplinary Care.--If you find problems in the area of comprehensive, interdisciplinary care, review staffing credentials and patterns. Consider looking further into the following Conditions for Coverage.

o Patient long-term program and patient care plan (V310).--How do the members of the professional team participate in the collaborative development of a long-term program and care plan for each patient? How is the patient involved in the development of his/her long-term program and care plan?

o Staff (V430).--Review staffing patterns. How does the facility determine the adequate number of trained personnel who are required to meet the needs of the patients. How does the facility determine that the staff have appropriate training and licensure?

o Minimal service requirements (V440).--Review documentation of social and nutritional services provided. How does the facility ensure that adequate dialysis services are being provided? How does the facility ensure that adequate laboratory, social, and nutritional services are provided to the patient?

C. Understanding of Facility Policies.--If the patients do not understand the facility's clinical and administrative policies, review the documents related to patient's rights. Consider looking further into the following Conditions for Coverage.

o Governing body and management (V110).--How does the facility ensure that the patient care policies cover the care of patients in medical and other emergencies? How does the governing body inform patients about the patient-related policies and procedures of the facility?

o Patients rights and responsibilities (V330).--Review documentation in patient records related to rights and responsibilities. How does the facility ensure that patients are informed of their rights? How does the facility educate patients about services available to them within the facility? What are the facility's policies and procedures about grievances? How are grievances investigated and addressed within the facility?

V. TASK 5-INTERVIEWS/OBSERVATIONS OF PERSONNEL

A. Role Coverage and Interdisciplinary Relationships.--If you find gaps in staff/role coverage, review staffing credentials, schedules, and patterns. Refer to Task 6 of the Basic Survey when selecting a sample for personnel interviews. Consider looking further into the following Conditions for Coverage.

o Staff (V430).--Review staffing patterns. How does the facility ensure that properly trained personnel are present in adequate numbers to meet the needs of the patients? How does the facility guarantee that the staff are appropriately trained and licensed?

o Minimal service requirements (V440).--Review documentation of these services. How does the facility ensure that it is providing adequate social services and nutritional services to meet the needs of the patients?

B. Training and Supervision.--If you find problems in training and supervision, review training documents. Consider looking further into the following Conditions for Coverage.

o Governing body (V110).--Review training documents. How does the facility ensure that the staff are adequately trained? How does the facility
ensure that all of the staff participate in educational programs on a regular basis? What is the staff supervisory structure? Who supervises trainees?

o Medical director (V420).--How does the medical director ensure adequate training in dialysis techniques?

C. Administrative Support.--If you find problems with administrative support, review personnel policies and procedures. Consider looking further into the following Conditions of Coverage.

o Governing body and management (V110).--Review personnel policies and procedures. Do the personnel policies and procedures support sound patient care and promote good personnel practices? Does the Chief Executive Officer (CEO) devote sufficient time to the oversight of the facility?

VII. TASK 6 REVIEW OF CLINICAL RECORDS

A. Dialysis Prescriptions.--If you find problems with the individualized dialysis prescriptions, review policies on prescriptive dialysis. Refer to Task 6 of the Basic Survey when selecting a sample for records review. Consider looking further into the following Conditions of Coverage.

o Governing body and management (V110).--How does the facility ensure that the physician responsible for the patient's medical supervision evaluates the patient's immediate and long-term needs and prescribes care?

o Physical environment (V380).--How does a facility ensure that there are sufficient individual delivery systems for the treatment of any patient requiring special dialysis solutions? If a facility only has a central batch delivery system, what agreements or arrangements does it have for the provision of individualized dialysis treatments?

o Director (V420).--How does the director or director-designate ensure adequate monitoring of the patient and the dialysis process? How does he/she ensure that each patient's dialysis prescription is individualized?

B. Long-Term Programs and Patient Care Plans.--If there are problems with the long-term program or the patient care plan, review the philosophy and process governing the long-term program development. Consider looking further into the following Condition of Coverage.

o Long-term program and patient care plan (V310).--How does the facility ensure that each patient participates in the development and renewal of his/her long-term program and patient care plan? How does the facility ensure that these programs and plans are interdisciplinary?

C. Treatment Records.--If there are problems with the treatment records, review the policies and procedures on medical records. Consider looking further into the following Condition of Coverage.

o Medical records (V350).--How are the medical records of the facility organized? How does the facility ensure that these records are accurate and complete? Are the records readily available for recording and retrieval? Who supervises the medical record system? Who ensures that records and reports are reviewed appropriately?

VII. TASK 7-REVIEW OF QUALITY ASSURANCE/IMPROVEMENT RECORDS

If you find deficiencies in a facility's quality assurance program, review the policies and procedures on quality assurance, review by-laws, minutes of the governing body, and organizational charts to track responsibilities for quality improvement activities.

o Governing body and management (V110).--How does the facility ensure that reports of incidents and accidents are maintained and reviewed periodically? What policies address quality improvement goals?

o Reuse (V200).--If the facility is reprocessing disposables, how does the facility maintain reports for its quality assurance and quality control activities? How and within what timeframes does the facility produce and analyze trends? How are reports distributed, reviewed, and used as documents for problem solving?

VIII. TASK 8-REVIEW OF OPERATIONAL LOGS

If you find problems in the areas of preventive maintenance or repair of equipment, review policies and procedures on maintenance and repair of equipment. Consider looking further into the following Conditions of Coverage.

o Physical environment (V380).--What is the program for preventive maintenance of equipment? What equipment is included in the preventive maintenance plans? How does the facility guarantee that all equipment is safe? Who is in charge of fixing equipment that needs repair?

o Reuse (V200).--What is the program for preventive maintenance of the reuse equipment? Who monitors the equipment maintenance and the repair of the equipment used in reuse?

IX. TASK 9-REVIEW OF PERSONNEL RECORDS

If you find personnel problems during your survey, review job descriptions, staff licenses, and personnel policies on health and training. Consider looking further into the following Conditions of Coverage.

o Governing body and management (V110).--How does the facility ensure that the personnel receive appropriate health monitoring and clinical supervision and ongoing training?

o Staff (V430).--How does the facility determine the adequate number of trained personnel who are required to meet the needs of the patients? How does the facility determine that the staff have appropriate training and licensure?

o Minimal service requirements (V440).--How does the facility ensure that adequate dialysis services are being provided? How does the facility ensure that adequate laboratory, social, and nutritional services are provided to the patient?

X. TASK 10-REVIEW OF AFFILIATIONS

If you find problems in the area of responsibilities to organizations outside of the facility, such as an ESRD Network organization or an organ procurement organization, review policies and documents related to responsibilities to organizations outside of the facility. Consider looking further into the following Conditions of Coverage.

o Governing body and management (V110).--How does the facility ensure appropriate involvement with organizations outside of the facility?

o Minimal service requirements (V440).--How does the facility participate in a patient registry program with an organ procurement organization?

o Compliance with other laws (V100).--How does the facility enforce other Federal, State, and local laws?

XI. TASK 11-ASSESSMENT OF SPECIAL SITUATIONS

If you find problems in the manner in which special situations are managed, review appropriate policies and medical records. Consider looking further into the following Conditions of Coverage.

o Medical director (V420).--Review the policies and the job description/contract which address the responsibilities of the Medical Director. Review medical records for evidence of the Medical Director's involvement in monitoring patients and the dialysis process. In facilities which provide service to patients of multiple physicians, the medical director's oversight should be reflected in facility administrative records, such as minutes of governing body activities and quality assurance. How does the Medical Director monitor dialysis patients and the dialysis process? How does the Medical Director monitor self dialysis patients? How does the Medical Director monitor staff physicians?

o Minimal service requirements (V440).--How does the facility provide adequate laboratory, social, and dietetic services to meet the individual patient needs? How does the facility provide support services for self dialysis? A renal dialysis center which treats pediatric patients must comply with appropriate requirements for disabled children under title V of the Act. How does the center comply with requirements under title V?

Part IV
THE INITIAL SURVEY PROTOCOL

THE INITIAL SURVEY PROTOCOL

The initial survey protocol is used for first surveys for new ESRD suppliers. This survey protocol can also be used for facilities that are changing ownership, management, location, or services. During the initial survey, many policies and procedures will be reviewed that you will not need to review again. These policies and procedures should ensure that the facility meets the basic safety and health standards of the regulations.

This survey emphasizes reviewing documents and protocols, observing the site, and interviewing staff. Patient interviews are a minor part of this survey protocol because there are usually only a few patients, and they will not have a history with a new facility.

THE COMPONENTS OF THE INITIAL SURVEY

Task 1 Tour for observations

Task 2 Record reviews

Task 3 Interviews

I. TASK 1-TOUR FOR OBSERVATIONS

Conduct the observational tour to make assessments about the physical layout of the facility. Determine if the physical layout is designed with consideration of infection control, safety, and emergency preparedness.

Observe the locations of the sinks and waste containers. Are paper towel holders, soap dispensers, and trash cans placed appropriately around the sinks? If hepatitis B-infected patients will be treated in the facility, observe how cross-contamination will be prevented. (V110, V380)

Note the area of patient treatment. Is there adequate space between patient chairs to provide emergency care in the event of an emergency, such as a drop in blood pressure, nausea, and/or vomiting. What emergency equipment is available in the unit? Note the patient reception/waiting area. Is there adequate space for wheel chair storage? Are patient restrooms available, clean, and handicapped-accessible? Is there a call system or other mechanism in the patient restroom to allow needed help to be summoned? (V110, V380)

Observe the reuse area if the facility will practice reuse. Observe the ventilation system. Note the storage areas for reprocessing materials, devices awaiting reprocessing, and reprocessed devices. Determine if the storage area minimizes deterioration, contamination, and breakage. Observe that durable gloves, eye protection, and protective clothing are available for use during reprocessing. Determine if an eye wash station, a respirator, and spill kit materials are available for use if needed. After the facility has been operational for several months, schedule a full reuse survey. (V200)

Observe the water treatment area. Observe the components of the water treatment and distribution system to ensure that they are compatible and will not leach toxic elements. Copper, zinc, brass, or aluminum components should not be used. Determine by observation and interview that there are no stagnant flow areas in the fluid distribution system that can't be easily sanitized. Observe that sampling ports are located after each component of the water treatment system. Observe where the bicarbonate concentrate is prepared and stored. (V380)

II. TASK 2-RECORD REVIEWS

Find out about the record-keeping system. How are the records organized? What policies have been established for charting and review? If the facility will be doing home training, how will records be maintained for the home patients? (V368, V451)

Review records and documents in the following areas:

o Cleanliness and Infection Control.--Review the policies and procedures regarding sanitation and infection control and prevention. How is a safe and sanitary environment ensured? (V110, V380)

o Safety and Emergency Preparedness.--Review the policies and procedures on safety and emergency preparedness. Does the facility have appropriate disaster and emergency plans for fire, equipment failure, and natural disaster? (V110, V380)

o Dialyzer Reuse.--Review policies and procedures for the reprocessing of hemodialyzers. What equipment and disinfectant has the facility selected if dialyzers are going to be reprocessed? How will the facility meet manufacturers' guidelines in its reprocessing? What parameters have been established for reprocessing? (V200)

o Water and Dialysate Treatment.--Review the policies and procedures on water treatment systems and equipment maintenance. How will the facility ensure that the water will be biologically and chemically acceptable? What

test results and equipment maintenance schedules will be maintained? Review initial water testing results for compliance with regulatory requirements. (V380)

o Clinical Records.--Review the policies and procedures on clinical records, the dialysis prescription, and the care planning process. Find out how the records are organized, used, and stored. How will the facility ensure that these records are accurate and complete? Will the records be readily available for recording and retrieval? Who supervises the medical record system? Who will ensure that the records are reviewed appropriately? (V350)

How is the patient's dialysis prescription determined, recorded, and reviewed? How will the patient and the multidisciplinary team participate in the care planning process, and how will team planning be recorded? (V110, V310, V420)

Where will data be recorded regarding fevers and chills, hospitalizations, device reactions, blood reactions? How and where will unusual incidents, medication errors, and patient grievances be recorded? How will appropriate agencies be notified? (V100, V110, V330)

o Quality Assurance/Improvement Records.--Review the policies and procedures on quality assurance/improvement. Review by-laws and organizational charts to track responsibilities for quality improvement activities. What quality assurance program has the facility established? How will the facility ensure that reports of incidents and accidents are maintained, reviewed, and acted upon? (V110, V200)

o Operational Logs.--Review the policies and procedures on maintenance and repair of equipment. Review records of the installation and calibration of dialysis equipment and automated reuse equipment. What equipment is included in the preventive maintenance plans? Who monitors equipment maintenance and the repair of equipment? (V380, V200)

o Personnel Records and Staffing.--Review job descriptions, staff schedules, staff licenses and credentials, employment contracts, staffing and supervision policies, and personnel policies on health and training. How did the facility determine the qualifications of their initial staff members? What orientation to this new facility has been provided? How does the facility determine that the staff have appropriate education and licensure? How does the facility ensure that personnel receive appropriate clinical supervision, health monitoring, and ongoing training? How does the facility ensure that adequate laboratory, social, and nutritional services are provided to the patient? Review planned staffing schedules to ensure that adequate coverage for the planned census of patients will be available (V110, V430, V440).

o Affiliation Agreements.--Review policies and documents related to responsibilities to organizations outside of the facility, such as the ESRD Network organization and the organ procurement organization in the area (V110, V440).

III. TASK 3-INTERVIEWS

Conduct interviews with the Medical Director, as well as other key staff persons, including nurses and technicians.

A. Interview with Reuse Technician.--Determine if the personnel involved in reprocessing exhibit that they have adequate training and/or experience to perform the assigned tasks (V200, V430).

o Ask the technician to describe the reprocessing procedures for dialyzers.

o Ask the technician some general questions regarding reuse. How long is the disinfectant stable after it is mixed? Once a dialyzer is reprocessed, how long can it remain on the shelf before being used?

o Ask the technician to describe his/her behavior if it is apparent that he/she cannot perform tasks or procedures properly. What would you do if you ran out of disinfectant? What would you do if the concentration of disinfectant in dialyzers after storage is too low? What would you do if you don't have enough room in the storage area? What would you do if you noticed that the port caps had popped off of the reprocessed dialyzer during storage?

o Ask the technician about records. Where do you record the date of each reprocessing step? Where do you record the results of testing device performance and safety?

o Ask the technician to describe the risks and actions associated with the toxic substances used in reprocessing. What toxic substances do you work with? What protective clothing do you wear and why? What would you do in the event of a large/small spill of toxic substances? Which personnel are aware of the risks and actions necessary in the handling of toxic substances?

o Ask the technician to describe the storage and handling of reprocessing chemicals. Where do you store the reuse chemicals? Are there certain temperatures which must be maintained in the storage area?

o Ask the technician about environmental safety. How do you ensure that toxic vapors from disinfectants are monitored as necessary? What steps are taken if the staff complains of discomfort from vapors?

B. Interview with Water Treatment Personnel.--Determine how the person in charge of water treatment functions (V380, V430).

o Ask about the daily start-up system. Who starts the system? Who tests the water? When do you test for chlorine/chloramines? What are the accepted limits? What do you do if you exceed those limits? Do you ever put the water treatment system in by-pass? Who determines if the system goes into by-pass? What happens to reuse if this occurs?

o Ask about the local water system. What contaminants are common in your local water? Does your local water department require a back flow preventor? How would your local water department contact you in the event of an emergency or change?

o Ask about water analysis. How does the facility test hemodialysis fluids (water, dialysate) for chemical, bacterial, and endotoxin concentrations? How often will each test be done? How does the medical director document his/her review? What action will be taken if the chemical analysis reveals levels of toxins above AAMI specified limits?

C. Interview with Patient Care/Nursing Staff.--Determine if the personnel involved in patient care/nursing care exhibit that they have adequate training and/or experience to perform the assigned tasks.

o Ask the nurse what the facility will do to prevent and control the spread of infections. What are the facility's policies and procedures

regarding hepatitis testing and control among patients and staff? How does the staff collect and dispose of waste? How does the staff dispose of needles? When and where is protective clothing worn? Where is protective clothing stored during breaks? (V110, V380)

o Ask the nurse about hazards and emergencies. Ask for a demonstration of the use of emergency equipment. What would you do if you observed a hazard or unsafe condition in the facility? What action would be taken if two patients (in proximate time) displayed serious unexplained symptoms? How would you evacuate patients? (V110, V380)

o Ask about nursing coverage. How will the facility ensure that there is sufficient staff coverage? How will the facility ensure that there is at least one licensed health professional present during dialysis treatments? How will the facility ensure that health professionals have credentials and authority to institute required emergency treatment procedures, such as changing a clotted dialyzer, administering intravenous medications or physicians orders, or conducting cardiac-pulmonary resuscitation? What actions will be taken when sick calls occur? (V110, V430)

o Ask about patient treatment. How are patients informed about their medical condition and treatment? How will patients be involved in the development of their long-term program and care plan? What provisions are made to ensure that patients are treated with respect and dignity? What orientation did patients receive regarding this new facility? (V310, V330)

o Ask about recording and assessing care. How are the records organized? What is recorded on a routine basis? How often? How do you know that medical records and laboratory reports are reviewed appropriately? What quality assurance/quality improvement system will the facility use? How do you ensure that care is assessed, problems are addressed, and improvements are made on a continual basis? (V110, V350)

D. Interview with the Medical Director.--Determine what medical direction is provided to the facility.

o Ask about monitoring care. How will medical coverage be provided to the patients? By whom? Where? How often? How will you supervise the medical staff? (V420)

o Ask about adequate treatment. How do you ensure that each patient receives an adequate dialysis? What standards do you use to prescribe dialysis treatments? How are you alerted to problems that a patient is having while on dialysis? When and how do you adjust an individual patient's dialysis prescription? How/when are you informed of laboratory values? (V1000, V3000, V420)

o Ask about training. How have you ensured adequate training of the staff in dialysis techniques? How have you participated in the training of staff/patients? What do you have planned for continuing education for the staff of this unit? (V110, V420)

o Ask about recording and assessing care. What system of recording is used by the physician staff? How do you ensure that care is assessed, problems are addressed, and improvements are made on a continual basis? (V110, V350, V420)

E. Interview with Administrative Staff.--Determine how the facility is administered.

o Ask about staffing. How will the staffing patterns developed by the facility ensure that properly trained personnel are present in adequate numbers to meet the needs of the patients? How did the facility ensure that the staff are adequately trained? What is the staff supervisory structure? Who supervises trainees? (V110)

o Ask about comprehensive care. How will the facility provide adequate laboratory, social, and dietetic services to meet the individual patient needs? How will members of the team participate in collaborative development of a long-term program and care plan for each patient? (V310, V440)

o Ask about patient rights. How will the facility ensure that patients are informed of their rights and responsibilities as patients? How will the facility educate patients about services available to them within the facility? What are the facility's policies and procedures about grievances? How will grievances be addressed within the facility? (V330)

F. Interview with the Social Worker.--Determine how social work services will be provided.

o Ask about services. How will you provide the mandated social work services to patients and their families? What is your expected caseload both initially and as the facility functions more fully? How will your caseload and schedule allow you the needed time to minimally provide the mandated services? (V444, V445, V446)

o Ask about supervision and support. What type of supervision will you have? What type of administrative support will you have? (V110)

o Ask about team role. How do you define your role on the team? (V310, V440)

o Ask about privacy. How will you ensure the patient's right to privacy in communications with you? (V330)

o Ask about recording and assessing care. What system of recording will you use? How will you ensure that care is assessed, problems are addressed, and improvements are made on a continual basis? (V110, V350)

G. Interview with the Dietitian.--Determine how nutritional services will be provided.

o Ask about services. How will you provide the mandated nutritional services to the patients? (V447, V448)

o Ask about team role. How do you define your role on the team? How is your role different from the role of the staff physicians and other patient care staff regarding nutritional services? (V310, V440)

o Ask about recording and assessing care. What system of recording will you use? How will you ensure that care is assessed, problems are addressed, and improvements are made on a continual basis? (V110, V350)

H. Interviews with Patients.--If patients are available for interviews, determine how they view the facility services.

o Ask about facility policies. How did you find out about the facility's administrative and clinical policies? If you had a problem at the facility, who would you talk with? What would you do if the problem wasn't fixed? Do you know about the facility's grievance procedure? Do you know about the network's grievance procedure? What would you do in case of a medical emergency at the facility? At home? What does the facility expect you to do in the case of a fire or other disaster? (V177, V179, V342, V406)

o Ask about clinical, individualized care. How did/will the facility assess your health? How will/did the facility make a medical plan for you? What things do you need to be careful of because of your renal disease and treatment? How is your access working? Do you have any concerns/problems with the needle puncture at your access site? If you experience clinical symptoms while on dialysis, such as itching, chills, fever, who do you tell? Do you feel safe? Do you feel well-cared-for here? (V145, V146, V177)

o Ask about comprehensive care. What members of the health care team have you met so far? How have/will each of them assist you with your renal management and treatment? What have you been told about your medical condition? About your treatment? What choices about health management and different treatment modalities have been presented to you? Who has talked to you about services that are covered under Medicare? Who has talked with you about rehabilitation possibilities? (V310, V333, V334, V335, V336, V337, V420, V430, V440)

Part V
THE INTERPRETIVE GUIDELINES

THE INTERPRETIVE GUIDELINES

The Interpretive Guidelines are a reference. As a reference, they may be used by the surveyor or the facility to delineate facility performance expectations and the interpretation of those expectations. Whereas the survey procedures delineate priority areas for surveys, the Interpretive Guidelines address all areas of the regulations.

The Interpretive Guidelines include three columns. The first column contains the survey tag number that corresponds to a respective item on the ESRD Facility Survey Report. The second column contains the wording of the regulation from Subpart U, 42 CFR §405.2000. The third column contains guidance to surveyors, including survey procedures and probes.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	Subpart U--Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services Sec. 405.2102 Definitions. As used in this subpart, the following definitions apply:	The definitions from the 42 Code of Federal Regulations, Part 405, are included here for ease of reference.
	Agreement.	A written document executed between an End-Stage Renal Disease (ESRD) facility and another facility in which the other facility agrees to assume responsibility for furnishing specified services to patients and for obtaining reimbursement for those services.
	Arrangement.	A written document executed between an ESRD facility and another facility in which the other facility agrees to furnish specified services to patients but the ESRD facility retains responsibility for those services and for obtaining reimbursement for them.
	Dialysis.	A process by which dissolved substances are removed from a patient's body by diffusion from one fluid compartment to another across a semipermeable membrane. The two types of dialysis that are currently in common use are hemodialysis and peritoneal dialysis.
	End-Stage Renal Disease (ESRD).	That stage of renal impairment that appears irreversible and permanent, and requires a regular course of dialysis or kidney transplantation to maintain life.
	ESRD facility. Such facilities are:	A facility which is approved to furnish at least one specific ESRD service (see definition of “ESRD service”)

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	(a) *Renal Transplantation Center.*	A hospital unit which is approved to furnish directly transplantation and other medical and surgical specialty services required for the care of the ESRD transplant patients, including inpatient dialysis furnished directly or under arrangement. A Renal Transplantation Center may also be a Renal Dialysis Center.
	(b) *Renal dialysis center.*	A hospital unit which is approved to furnish the full spectrum of diagnostic, therapeutic, and rehabilitative services required for the care of ESRD dialysis patients (including inpatient dialysis furnished directly or under arrangement). A hospital need not provide renal transplantation to qualify as a renal dialysis center.
	(c) *Renal dialysis facility.*	A unit which is approved to furnish dialysis service(s) directly to ESRD patients.
	(d) *Self-dialysis unit.*	A unit that is part of an approved renal transplantation center, renal dialysis center, or renal dialysis facility, and furnishes self-dialysis services.
	(e) *Special purpose renal dialysis facility.*	A renal dialysis facility which is approved under 42 CFR §405.2164 to furnish dialysis at special locations on a short-term basis to a group of dialysis patients otherwise unable to obtain treatment in the geographical area. The special locations must be either special rehabilitative (including vacation) locations serving ESRD patients temporarily residing there, or locations in need of ESRD facilities under emergency circumstances.

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	ESRD service. The type of care or services furnished to an ESRD patient. Such types of care are:	
	(a) *Transplantation service.*	A process by which (1) a kidney is excised from a live or cadaveric donor, (2) that kidney is implanted in an ESRD patient, and (3) supportive care is furnished to the living donor and to the recipient following implantation.
	(b) *Dialysis service*-- (1) Inpatient dialysis	 Dialysis which, because of medical necessity, is furnished to an ESRD patient on a temporary inpatient basis in a hospital;
	(2) *Outpatient dialysis.* Outpatient dialysis includes: (i) *Staff-assisted dialysis.* (ii) *Self-dialysis.*	Dialysis furnished on an outpatient basis at a renal dialysis center or facility. Dialysis performed by the staff of the center or facility. Dialysis performed, with little or no professional assistance, by an ESRD patient who has completed an appropriate course of training.
	(3) *Home dialysis.*	Dialysis performed by an appropriately trained patient at home.
	(c) *Self-dialysis and home dialysis training;.*	A program that trains ESRD patients to perform self-dialysis or home dialysis with little or no professional assistance, and trains other individuals to assist patients in performing self-dialysis or home dialysis.
	Furnishes directly.	The ESRD facility provides the service through its own staff and employees, or through individuals who are under direct contract to furnish such services personally for the facility (i.e., not through “agreements” or “arrangements”).

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	Furnishes on the premises.	The ESRD facility furnishes services on its main premises; or on its other premises that are (a) contiguous with or in immediate proximity to the main premises, and under the direction of the same professional staff and governing body as the main premises, or (b) approved on a time-limited basis as a special purpose renal dialysis facility.
	Histocompatibility testing.	Laboratory test procedures which determine compatibility between a potential organ donor and a potential organ transplant recipient.
	Medical care criteria.	Predetermined elements against which aspects of the quality of a medical service may be compared. They are developed by professionals relying on professional expertise and on the professional literature.
	Medical care norms.	Numerical or statistical measures of usual observed performance. Norms are derived from aggregate information related to the health care provided to a large number of patients over a period of time.
	Medical care standards.	Professionally developed expressions of the range of acceptable variation from a norm or criterion.
	Medical care evaluation study (MCE).	Review of health care services, usually performed retrospectively, in which an indepth assessment of the quality and/or utilization of such services is made.
	Network, ESRD.	All Medicare-approved ESRD facilities in a designated geographic area specified by HCFA.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	Network organization.	The administrative governing body to the network and liaison to the Federal government.
	Organ procurement.	The process of acquiring donor kidneys. (See definition of Organ Procurement Organization in §485.302 of this chapter.)
	Qualified personnel.	Personnel that meet the requirements specified by the following:
	(a) *Chief executive officer*.	A person who: (1) Holds at least a baccalaureate degree or its equivalent, and has at least 1 year of experience in an ESRD unit; or (2) Is a registered nurse or physician director as defined in this definition; or (3) As of September 1, 1976, has demonstrated capability by acting for at least 2 years as a chief executive officer in a dialysis unit or transplantation program.
	(b) *Dietitian.*	A person who: (1) Is eligible for registration by the American Dietetic Association under its requirements in effect on June 3, 1976, and has at least 1 year of experience in clinical nutrition; or (2) Has a baccalaureate or advanced degree with major studies in food and nutrition or dietetics, and has at least 1 year of experience in clinical nutrition.

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	(c) *Medical record practitioner.*	A person who: (1) Has graduated from a program for Medical Record Administrators accredited by the Council on Medical Education of the American Medical Association and the American Medical Record Association, and is eligible for certification as a Registered Record Administrator (RRA) by the American Medical Record Association under its requirements in effect on June 3, 1976; or (2) Has graduated from a program for Medical Record Technicians approved jointly by the Council on Medical Education of the American Medical Association and the American Medical Record Association, and is eligible for certification as an Accredited Record Technician (ART) by the American Medical Record Association under its requirements in effect June 3, 1976; or (3) Has successfully completed and received a satisfactory grade in the American Medical Record Association's Correspondence Course for Medical Record Personnel approved by the Accrediting Commission of the National Home Study Council, and is eligible for certification as an Accredited Record Technician by the American Medical Record Association under its requirements in effect June 3, 1976.
	(d) *Nurse responsible for nursing service.*	A person who is licensed as a registered nurse by the State in which practicing, and: (1) Has at least 12 months of experience in clinical nursing, and an additional 6 months of experience in nursing care of the patient with permanent kidney failure or undergoing kidney transplantation, including training in and experience with the dialysis process; or (2) Has 18 months of experience in nursing care of the patient on maintenance dialysis, or in nursing care of the patient with a kidney transplant, including training in and experience with the dialysis process; or (3) If the nurse responsible for nursing service is in charge of self-care dialysis training, at least 3 months of the total required ESRD experience is in training patients in self-care.

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	(e) *Physician-director.*	A physician who: (1) Is board eligible or board certified in internal medicine or pediatrics by a professional board, and has had at least 12 months of experience or training in the care of patients at ESRD facilities; or (2) During the 5-year period prior to September 1, 1976, served for at least 12 months as director of a dialysis or transplantation program; or (3) In those areas where a physician who meets the definition in paragraph (1) or (2) of this definition is not available to direct a participating dialysis facility, another physician may direct the facility subject to the approval of the Secretary.
	(f) *Social worker.*	A person who is licensed, if applicable, by the State in which practicing, and: (1) Has completed a course of study with specialization in clinical practice at, and holds a masters degree from, a graduate school of social work accredited by the Council on Social Work Education; or (2) Has served for at least 2 years as a social worker, 1 year of which was in a dialysis unit or transplantation program prior to September 1, 1976, and has established a consultative relationship with a social worker who qualifies under paragraph (f)(1) of this definition.
	(g) *Transplantation surgeon.*	A person who: (1) Is board eligible or board certified in general surgery or urology by a professional board; and (2) Has at least 12 months training or experience in the performance of renal transplantation and the care of patients with renal transplants.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
V100	§405.2135 Condition: Compliance with Federal, state and local laws and regulations. The ESRD facility is in compliance with applicable Federal, State and local laws and regulations.	Interpretive Guidelines: §405.2135 Failure of an ESRD facility to meet an applicable Federal, State, or local law may be cited when the Federal, State, or local authority having jurisdiction has made a determination of non-compliance and has taken a final adverse action (sanction) as a result and there is continued noncompliance. If State law provides for the licensure of ESRD facilities, request to see a copy of the current license. If you suspect that you have observed non-compliance with an applicable Federal law related to the provider's ESRD program, notify the HCFA RO. The RO will notify the appropriate Federal agency of your observations. Applicable Federal laws include the Food and Drug Administration's (FDA) Medical Device Reporting requirements, the Occupational Safety and Health Administration's (OSHA's) environmental and training requirements, and the Office of Civil Rights' (OCR's) anti-discrimination requirements. Under the FDA's Medical Device Reporting requirements, the facility must notify the FDA (1-800-638-6725) and the manufacturer if a medical device may have caused or contributed to a death using User Facility reporting requirements. If a device may have caused and/or contributed to a serious injury or serious illness, the facility notifies the manufacturer if they know the name of the manufacturer, or the FDA if they do not know the name of the manufacturer.
V101	(a) Standard: Licensure. Where State or applicable local law provides for the licensing of ESRD facilities, the facility is: (1) Licensed pursuant to such law; or	Interpretive Guidelines: §405.2135(a) An ESRD facility is responsible for meeting all State and local laws.
V102	(2) Approved by the agency of such State or locality responsible for such licensing as meeting the standards established for such licensing.	§405.2135(a)(2)

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
V103	(b) Standard: Licensure or registration of personnel. Each staff member is currently licensed or registered in accordance with applicable law.	§405.2135(b)
V104	(c) Standard: Conformity with other laws. The facility is in conformity with applicable laws and regulations pertaining to fire safety, equipment, and other relevant health and safety requirements.	§405.2135(c)
V110	§405.2136 Condition: Governing body and management. The ESRD facility is under the control of an identifiable governing body, or designated person(s) so functioning, with full legal authority and responsibility for the governance and operation of the facility.	Interpretive Guidelines: §405.2136 If a facility is owned by a larger corporate entity, determine who is responsible for the operations, policies, and procedures at the facility. Does the facility follow corporate-based policies or does the facility follow the policies of its own governing body that differ from the corporate entity? How do these two governing bodies interact? It is not required that there be a corporate and a local governing body; however, it is important to know which has the ultimate authority for the governance and operation of the facility.
V111	The governing body adopts and enforces rules and regulations relative to its own governance.	Interpretive Guidelines: §405.2136 If in doubt about a facility's particular practice, review the policies and procedures relative to the questionable practice to see if they are in keeping with standard quality of care. Survey Procedures and Probes: §405.2136 How does the governing body enforce the rules?
V112	And to the health care and safety of patients,	Interpretive Guidelines: §405.2136 The governing body should assure that the facility has and maintains an ongoing quality assurance program that continually monitors its operations, and ensures the delivery of quality care to ESRD patients.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
V113	To the protection of the patients' personal and property rights, and	§405.2136
V114	To the general operation of the facility.	§405.2136
V115	The governing body receives and acts upon recommendations from the network organization.	§405.2136
V116	The governing body appoints a chief executive officer who is responsible for the overall management of the facility.	§405.2136
V117	(a) Standard: Disclosure of ownership. The ESRD facility supplies full and complete information to the State survey agency (§405.1902(a)) as to the identity of: (1) Each person who has any direct or indirect ownership interest of 10 percentum or more in the facility, or who is the owner (in whole or in part) of any mortgage, deed of trust, note, or other obligation secured (in whole or in part) by the facility or any of the property or assets of the facility;	Interpretive Guidelines: §405.2136(a)(1) Review the HCFA-1513 for completeness and compliance with this standard. Information required to be disclosed in this standard, but not required on the HCFA-1513 should be disclosed to the State survey agency in writing and attached to the HCFA-1513.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
V118	(2) Each officer and director of the corporation, if the facility is organized as a corporation; and	§405.2136(a)(2)
V119	(3) Each partner, if the facility is organized as a partnership;	§405.2136(a)(3)
V120	And promptly reports to the State survey agency any changes which would affect the current accuracy of the information so required to be supplied.	Survey Procedures and Probes: §405.2136(a)(3) Has the facility made any changes in its ownership since the last survey? Did they report those changes? Cite here if the facility made changes in its ownership and did not report those changes to the State survey agency.
V121	(b) Standard: Operational objectives. The operational objectives of the ESRD facility, including the services that it provides, are established by the governing body and delineated in writing. The governing body adopts effective administrative rules and regulations that are designed to safeguard the health and safety of patients and to govern the general operations of the facility, in accordance with legal requirements.	§405.2136(b)
V122	Such rules and regulations are in writing and dated.	§405.2136(b)

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
V123	The governing body ensures that they are operational, and that they are reviewed at least annually and revised as necessary.	§405.2136(b)
V124	If the ESRD facility is engaged in the practice of hemodialyzer reuse, the governing body ensures that there are written policies and procedures with respect to reuse, to assure that recommended standards and conditions are being followed, and requires that patients be informed of the policies and procedures.	Interpretive Guidelines: §405.2136(b) The review of this requirement should be coordinated with §405.2138(a), Patients' rights and responsibilities, and §405.2150, Reuse of hemodialyzers and other dialysis supplies.
V125	(1) The objectives of the facility are formulated in writing and clearly stated in documents appropriate for distribution to patients, facility personnel, and the public.	§405.2136(b)(1)
V126	(2) A description of the services provided by the facility, together with a categorical listing of the types of diagnostic and therapeutic procedures that may be performed, is readily available upon request to all concerned.	§405.2136(b)(2)

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
V127	(3) Admission criteria that insure equitable access to services are adopted by the facility and are readily available to the public. Access to the self-dialysis unit is available only to patients for whom the facility maintains patient care plans (see 405.2137).	Interpretive Guidelines: §405.2136(b)(3) An ESRD facility must comply with provisions of §504 of the Rehabilitation Act of 1973. Specifically, The Rehabilitation Act requires that no otherwise qualified person with a disability be denied access to, or the benefits of, or be subject to discrimination by any program or activity provided by any institution or entity receiving federal funds. This provision ensures that patients with the human immunodeficiency virus (HIV) cannot be denied access to care because of their HIV status. The admission policies should delineate which patients will or will not be treated by the facility. These policies must apply to all patients equally, without regard to their health status or method of payment, e.g., private pay, Medicare and Medicaid. If the admission policies of the facility specifically exclude or define practices that constitute unequal treatment of HIV-positive patients, cite noncompliance here and notify the HCFA RO's Office of Civil Rights for followup. If you suspect violation of civil rights that is not specific to the admission criteria of the facility but appears to be facility practice, do not cite noncompliance here. Refer the situation to the HCFA RO, Office of Civil Rights for followup. Survey Procedures and Probes: §405.2136(b)(3) What evidence is there to indicate that the admission policies are applied equitably to all individuals?
V128	(4) The operational objectives and administrative rules and regulations of the facility are reviewed at least annually and revised as necessary by the administrative staff, medical director, and other appropriate personnel of the facility, and are adopted when approved by the governing body.	Survey Procedures and Probes: §405.2136(b)(4) How long has it been since the facility's operational objectives have been reviewed? Is the review documented?
V129	(c) Standard: Chief executive officer. The governing body appoints a qualified chief executive officer who, as the ESRD facility's administrator: Is responsible for the overall management of the facility; enforces the rules	Interpretive Guidelines: §405.2136(c) The chief executive officer (CEO) as defined at §405.2102 is a person who: (1) Holds at least a baccalaureate degree or its equivalent and has at least one year of experience in an ESRD unit; (2) is a registered nurse or physician director as defined in the regulations; or (3) as of September 1, 1976, has demonstrated capability by acting for at least two years as a chief executive officer in a dialysis unit or transplantation unit.

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	and regulations relative to the level of health care and safety of patients, and to the protection of their personal and property rights; and plans, organizes, and directs those responsibilities delegated to him by the governing body.	Survey Procedures and Probes: §405.2136(c) Each ESRD facility has peer review-type oversight that is separate from the RO survey and certification program to protect the individual ESRD patient's personal and property rights. This oversight is provided by the 18 ESRD Network offices strategically located throughout the country. In general, the Network monitors an ESRD facility for compliance with patient-focused goals and activities it has previously determined for that facility. What are the facility's Network goals? How does the CEO assure Network interacttion with the facility? How does the CEO monitor these goals? How does the CEO monitor the facility's action on the recommendations of the Network?
V130	Through meetings and periodic reports, the chief executive officer maintains on-going liaison among the governing body, the medical and nursing personnel, and other professional and supervisory staff of the facility, and acts upon recommendations made by the medical staff and the governing body.	Survey Procedures and Probes: §405.2136(c) How does the CEO communicate with the governing body and with the professional and administrative staff?
V131	In the absence of the chief executive officer, a qualified person is authorized in writing to act on the officer's behalf.	Interpretive Guidelines: §405.2136(c) The qualified alternate must meet the requirements specified for the CEO. (See definition at §405.2102, page H-43).
V132	(1) The governing body delineates in writing the responsibilities of the chief executive officer, and ensures that he/she is sufficiently free from other duties to provide effective direction and management of the operations and fiscal affairs of the facility.	§405.2136(c)(1)
V133	(2) The chief executive officer serves on a full-time or part-time basis, in accordance with the scope of the facility's operations and administrative needs, and devotes sufficient time to the conduct of such responsibilities.	§405.2136(c)(2)

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V134	(3) The responsibilities of the chief executive officer include but are not limited to: (i) Implementing the policies of the facility and coordinating the provision of services, in accordance with delegations by the governing body.	§405.2136(c)(3)(i)
V135	(ii) Organizing and coordinating the administrative functions of the facility, redelegating duties as authorized, and establishing formal means of accountability for those involved in patient care.	Survey Procedures and Probes: §405.2136(c)(3)(ii) How does the CEO ensure all staff are accountable for jobs assigned? How does the Quality Assurance/Quality Improvement (QA/QI) program monitor those involved in patient care?
V136	(iii) Authorizing expenditures in accordance with established policies and procedures.	§405.2136(c)(3)(iii)
V137	(iv) Familiarizing the staff with the facility's policies, rules, and regulations, and with applicable Federal, State, and local laws and regulations.	Survey Procedures and Probes: §405.2136(c)(3)(iv) The CEO is ultimately responsible for ensuring that policies are put into practice. Are the facility's policies being implemented, i.e., what is the staff's understanding of facility policies? Do staff interviews reveal that policies are being put into practice? Do new staff receive facility policy information at orientation? How is the staff updated with new information or changes in current policy?
V138	(v) Maintaining and submitting such records and reports, including a chronological record of services provided to patients, as may be required by the facility's internal committees and governing body, or as required by the Secretary.	§405.2136(c)(3)(v)

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V139	(vi) Participating in the development, negotiation, and implementation of agreements or contracts into which the facility may enter, subject to the approval by the governing body of such agreements or contracts.	§405.2136(c)(3)(vi)
V140	(vii) Participating in the development of the organizational plan and ensuring the development and implementation of an accounting and reporting system, including annual development of a detailed budgetary program, maintenance of fiscal records, and quarterly submission to the governing body of reports of expenses and revenues generated through the facility's operation.	§405.2136(c)(3)(vii)
V141	(viii) Ensuring that the facility employs the number of qualified personnel needed; that all employees have appropriate orientation to the facility and their work responsibilities upon employment; and that they have an opportunity for continuing education and related development activities.	Survey Procedures and Probes: §405.2136(c)(3)(viii) What process does the facility have to evaluate whether the types/mix of staff employed are adequate to meet patient's needs? What does the orientation program for new employees consist of? What continuing educational programs are offered to the staff? How are learning needs identified? How are skills/competencies demonstrated? Is QA/QI data used to develop continuing education programs?
V142	(d) Standard: Personnel policies and procedures. The governing body, through the chief executive officer of the ESRD facility, is responsible for maintaining and implementing written personnel policies and procedures that support sound patient care and	§405.2136(d)

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V143	Promote good personnel practices.	Survey Procedures and Probes: §405.2136(d) Based on observation, are personnel practices consistent with procedures for sound patient care?
V144	These policies and procedures ensure that: (1) All members of the facility's staff are qualified to perform the duties and responsibilities assigned to them and meet such Federal, State, and local professional requirements as may apply.	Survey Procedures and Probes: §405.2136(d)(1) How does the facility ensure that all staff are appropriately licensed? Do the health professional staff have the appropriate credentials and authority to administer required treatment procedures?
V145	(2) A safe and sanitary environment for patients and personnel exists, and	Interpretive Guidelines: §405.2136(d)(2) The facility policies should define which, and how often, personnel will require periodic health examinations. Specifically, these policies should define how often health examinations will be given to personnel to detect hepatitis and other infectious diseases. Personnel records should reflect the health status of the personnel. Due to the confidential aspects of HIV (AIDS) infections, the facility should have procedures specifically developed for this problem. Survey Procedures and Probes: §405.2136(d)(2) Policies should also promote cleanliness of the facility. Based on observation of patient treatment areas, is the equipment clean?. Are the floors and linens clean? Is there evidence of any water hazards, i.e., puddles on the floor, areas of standing water? Are reuse rooms kept clean?
V146	Reports of incidents and accidents to patients and personnel are reviewed to identify health and safety hazards.	Interpretive Guidelines: §405.2136(d)(2) The incident and accident reports are an integral part of the facility's quality assurance/improvement program. Survey Procedures and Probes: §405.2136(d)(2) How does the facility ensure that incident and accident reports are reviewed appropriately and corrective/preventive action taken, if needed?

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V147	Health supervision of personnel is provided, and they are referred for periodic health examinations and treatments as necessary or as required by Federal, State, and local laws.	Interpretive Guidelines: §405.2136(d)(2) While not a requirement of the HCFA regulations, the Centers for Disease Control and Prevention (CDC) recommends and OSHA requires that the facility offer the appropriate vaccinations for hepatitis. OSHA mandates that the facility offer the vaccine at no charge and documents employee choice. Coordinate the review of this requirement with §405.2135(c).
V148	Procedures are established for routine testing to ensure detection of hepatitis and other infectious diseases.	Survey Procedures and Probes: §405.2136(d)(2) Are procedures available documenting the facility's policy for ensuring the health of its personnel? How often is testing done?
V149	(3) If the services of trainees are utilized in providing ESRD services, such trainees are under the direct supervision of qualified professional personnel.	§405.2136(d)(3)
V150	(4) Complete personnel records are maintained on all personnel. These include health status reports,	Survey Procedures and Probes: §405.2136(d)(4) What evidence is there that employees received periodic health examinations and tests for hepatitis or other infectious diseases?
V151	Resumes of training and experience, and	§405.2136(d)(4)
V152	Current job descriptions that reflect the employees' responsibilities and work assignments.	Survey Procedures and Probes: §405.2136(d)(4) How does the facility document that each staff member has reviewed his/her current job description?

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V153	(5) Personnel policies are written and made available to all personnel in the facility. The policies provide for an effective mechanism to handle personnel grievances.	§405.2136(d)(5)
V154	(6) All personnel of the facility participate in educational programs on a regular basis. These programs cover the initial orientation, and continuing inservice training, including procedures for infection control. Records are maintained showing the content of training sessions and the attendance at such sessions.	Survey Procedures and Probes: §405.2136(d)(6) Coordinate the review of this requirement with §405.2161(b)(2). Interview nursing and technical staff about training and supervision. What training do they have for their job? What qualifications are required for someone to do their job? Who answers questions and provides direction if staff can't handle something?
V155	(7) Personnel manuals are maintained, periodically updated, and made available to all personnel involved in patient care.	Survey Procedures and Probes: §405.2136(d)(7) After observing patient care practices and/or interviewing staff or patients, do personnel policy manuals reflect current practice?
V156	(e) Standard: Use of outside resources. If the ESRD facility makes arrangements for the provision of a specific service as authorized in this subpart, the responsibilities, functions, objectives, and the terms of each arrangement, including financial provisions and charges, are delineated in a document signed by an authorized representative of the facility and the person or agency providing the service.	Interpretive Guidelines: §405.2136(e) Laboratory analyses of patients' blood and urine specimens and cultures of water and dialysate specimens are frequently handled by outside laboratories. It is important for the facility to monitor these services and results in order to ensure that testing is done in accordance with appropriate procedures. For example, facilities should be aware of procedures used to culture water and whether or not the culturing procedures are in compliance with AAMI guidelines. Testing done on patient specimens to assess health status must be performed in a CLIA-certified laboratory.

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	The chief executive officer when utilizing outside resources, as a consultant, assures that he is apprised of recommendations, plans for implementation, and continuing assessment through dated, signed reports, which are retained by the chief executive officer for follow-up action and evaluation of performance.	Survey Procedures and Probes: §405.2136(e) How does the facility ensure the continuing assessment of services provided by outside resources?
V157	(f) Standard: Patient care policies. The ESRD facility has written policies, approved by the governing body, concerning the provision of dialysis and other ESRD services to patients.	§405.2136(f)
V158	The governing body reviews implementation of policies periodically to ensure that the intent of the policies is carried out.	Survey Procedures and Probes: §405.2136(f) What evidence is there that indicates that the governing body critically examines operating policies to determine whether ESRD policies are current and responsive to the needs of the patient? What evidence, if any, is there that these policies have been implemented?
V159	These policies are developed by the physician responsible for supervising and directing the provision of ESRD services, or the facility's organized medical staff (if there is one), with the advice of (and with provision for review of such policies from time to time, but at least annually, by) a group of professional personnel associated with the facility, including, but not limited to, one or more physicians and one or more registered nurses experienced in rendering ESRD care.	Survey Procedures and Probes: §405.2136(f) If you identify questionable practices during your survey, review the applicable policies. Does facility practice reflect current policy? Determine who developed the policies and when they were last reviewed.

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V161	(1) The patient care policies cover the following: (i) Scope of services provided by the facility (either directly or under arrangement).	§405.2136(f)(1)(i)
V162	(ii) Admission and discharge policies (in relation to both in-facility care and home care).	§405.2136(f)(1)(ii)
V163	(iii) Medical supervision and physician services.	§405.2136(f)(1)(iii)
V164	(iv) Patient long term programs, patient care plans and methods of implementation.	Survey Procedures and Probes: §405.2136(f)(1)(iv) Do the policies governing the patient long-term programs and patient care plans reflect regulatory requirements, i.e., do they reflect the requirements specified at Vtags 185 through 205?
V165	(v) Care of patients in medical and other emergencies.	§405.2136(f)(1)(v)
V166	(vi) Pharmaceutical services.	§405.2136(f)(1)(vi)
V167	(vii) Medical records (including those maintained in the ESRD facility and in the patients' homes, to ensure continuity of care).	§405.2136(f)(1)(vii)

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V168	(viii) Administrative records.	§405.2136(f)(1)(viii)
V169	(ix) Use and maintenance of the physical plant and equipment.	§405.2136(f)(1)(ix)
V170	(x) Consultant qualifications, functions, and responsibilities.	§405.405.2136(f)(1)(x)
V171	(xi) The provision of home dialysis support services, if offered (see §405.2163(e)).	§405.2136(f)(1)(xi)
V172	(2) The physician-director of the facility is designated in writing to be responsible for the execution of patient care policies. If the responsibility for day-to-day execution of patient care policies has been delegated by a physician director to (or, in the case of a self-dialysis unit, to another licensed health practitioner) a registered nurse, the physician-director provides medical guidance in such matters.	Survey Procedures and Probes: §405.2136(f)(2) What evidence is there that the physician-director assumes responsibility for executing patient care policies?

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V173	(3) The facility policy provides that, whenever feasible, hours for dialysis are scheduled for patient convenience and that arrangements are made to accommodate employed patients who wish to be dialyzed during their non-working hours.	§405.2136(f)(3)
V174	(4) The governing body adopts policies to ensure there is evaluation of the progress each patient is making towards the goals stated in the patient's long-term program and patient's care plan (see §405.2137(a)). Such evaluations are carried out through regularly scheduled conferences, with participation by the staff involved in the patient's care.	Survey Procedures and Probes: §405.2136(f)(4) Look for evidence that staff meets regularly to evaluate the progress each patient is making towards the goals in their long-term program and patient care plan. What evidence is there that the patient care plan is impacted, reviewed and updated as a result of care planning meetings?
V175	(g) Standard: Medical supervision and emergency coverage. The governing body of the ESRD dialysis and/or transplant facility ensures that the health care of every patient is under the continuing supervision of a physician and	Interpretive Guidelines: §405.2136(g) The statutory requirement that every patient be under the care of a physician is extended to non-hospital based facilities by this regulation. If physician extenders are used, they cannot replace the physician when medical supervision is indicated. Survey Procedures and Probes: §405.2136(g) Ensure that the staff have been able to contact a physician when appropriate. Review clinical records to determine if dialysis prescriptions are individualized.
V176	That a physician is available in emergency situations.	Survey Procedures and Probes: §405.2136(g) Ask patients who they contact in the event of an emergency.

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V177	(1) The physician responsible for the patient's medical supervision evaluates the patient's immediate and long-term needs and on this basis prescribes a planned regimen of care which covers indicated dialysis and other ESRD treatments, services, medication, diet, special procedures recommended for the health and safety of the patient, and plans for continuing care and discharge.	Interpretive Guidelines: §405.2136(g)(1) Survey this requirement in conjunction with §405.2137 - Patient long-term program and patient care plan. Survey Procedures and Probes: §405.2136(g)(1) Review the long-term programs and patient care plans. How are the long-term programs and patient care plans individualized for each patient? How does the patient care plan reflect an assessment of patient's needs? How does the patient care plan reflect changes in a patient's needs? How does the long-term program reflect an assessment of the patient's preferences for a suitable modality and a suitable setting? Review written orders. Has the physician prescribed an individualized program of ESRD care for each patient? Are there written orders for dialysis treatments, services, medications and diet?
V178	Such plans are made with input from other professional personnel involved in the care of the patient.	Survey Procedures and Probes: §405.2136(g)(1) Does the interdisciplinary team demonstrate input into the patients' care plans and long term programs?
V179	(2) The governing body ensures that there is always available medical care for emergencies, 24 hours a day, 7 days a week. There is posted at the nursing/monitoring station a roster with the names of the physicians to be called, when they are available for emergencies, and how they can be reached.	Survey Procedures and Probes: §405.2136(g)(2) If only one physician is on the staff, find out what plan has been developed for coverage for that physician for illness/holidays.

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V180	(h) Standard: Medical staff. The governing body of the ESRD facility designates a qualified physician (see §405.2102) as director of the ESRD services; the appointment is made upon the recommendation of the facility's organized medical staff, it there is one.	Interpretive Guidelines: §405.2136(h) A qualified physician director is defined at §405.2102 as a physician who: (1) Is board eligible or board certified in internal medicine or pediatrics by a professional board, and has had at least 12 months of experience or training in the care of patients at ESRD facilities; (2) During the 5-year period prior to September 1, 1976, served at least 12 months as director of a dialysis or transplantation program; or (3) In those areas where a physician who meets the definition in paragraph (1) or (2) of this definition is not available to direct a participating facility, another physician may direct the facility, subject to the approval of the Secretary.
V181	The governing body establishes written policies regarding the development, negotiation, consummation, evaluation, and termination of appointments to the medical staff.	Survey Procedures and Probes: §405.2136(h) How does the medical director supervise the staff physicians? What system is in place to ensure that each physician provides individualized patient care?
V185	§405.2137 Condition: Patient long-term program and patient care plan. Each facility maintains for each patient a written long-term program and a written patient care plan to ensure that each patient receives the appropriate modality of care and the appropriate care within that modality. The patient, or where appropriate, parent or legal guardian is involved with the health team in the planning of care.	§405.2137
V186	A copy of the current program and plan accompany the patient on interfacility transfer.	Interpretive Guidelines: §405.2137 The intent of this requirement is for transfer of information between different facilities and between centers and facilities. An ESRD facility that admits a patient to a center would send basic records to that center within one working day and vice versa. If the center has an outpatient facility on campus, it is expected that the inpatient record would include pertinent information, including the current patient care plan.

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V187	(a) Standard: Patient long-term program. There is a written long-term program representing the selection of a suitable treatment modality (i.e., dialysis or transplantation) and dialysis setting (e.g., home, self-care) for each patient.	Interpretive Guidelines: §405.2137(a) The long-term program presents the rationale for the selection/change of a modality for ESRD treatment.
V188	(1) The program is developed by a professional team which includes but is not limited to the physician director of the dialysis facility or center where the patient is currently being treated, a physician director of a center or facility which offers self-care dialysis training (if not available at the location where the patient is being treated), a transplant surgeon, a qualified nurse responsible for nursing services, a qualified dietitian and a qualified social worker.	Interpretive Guidelines: §405.2137(a)(1) The long-term program should be based upon the medical, nutritional, and social evaluation of the patient. There should be evidence that the members of the health care team participated in the evaluation of the patient and that the program was agreed to by the members of the team. There should also be an indication that the patient was involved. A qualified physician director is defined at §405.2102 or see V180. A qualified transplantation surgeon is defined at §405.2102 as a physician who: (1) is board eligible or board certified in general surgery or urology by a professional board; and (2) has at least 12 months training or experience in the performance of renal transplantation and the care of patients with renal transplants. The record must indicate the transplant surgeon's participation to ensure that, consistent with the regulations, the transplant surgeon has participated in determining the selection of the suitable treatment modality. Criteria for exclusion from or inclusion in an evaluation for transplant may be developed by the transplant surgeon. These criteria may then be used by the transplant surgeon's designee (who could be a transplant coordinator or the treating nephrologist) to screen patients. If a designee for the surgeon participates in place of the surgeon on the development of the long-term program, the record must show that the criteria developed by the surgeon were followed in the development of the plan. The transplant surgeon's signature following review is one way to do this. If, when the designee is used, the facility can establish this in other ways, then the surgeon does not have to sign.

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		Interpretive Guidelines: §405.2137(a)(1) continued A qualified nurse responsible for nursing services is defined at §405.2102 as a person who: is licensed as a registered nurse by the State in which practicing, and (1) has at least 12 months of experience in clinical nursing, and an additional 6 months of experience in nursing care of the patient with permanent kidney failure or undergoing kidney transplantation, including training in and experience with the dialysis process; or (2) has 18 months of experience in nursing care of the patient on maintenance dialysis, or in nursing care of the patient with a kidney transplant, including training in and experience with the dialysis process; and (3) if the nurse responsible for nursing service is in charge of self-care dialysis training, at least 3 months of the total required ESRD experience is in training patients in self-care. A qualified dietitian is defined at §405.2102 as a person who: (1) Is eligible for registration by the American Dietetic Association under its requirements in effect on June 3, 1976, and has at least one year of experience in clinical nutrition; or (2) Has a baccalaureate or advanced degree with major studies in food and nutrition or dietetics, and has at least one year of experience in clinical nutrition. A qualified social worker is defined at §405.2102 as a person who: Is licensed, if applicable, by the State in which practicing, and (1) Has completed a course of study with specialization in clinical practice at, and holds a masters degree from a graduate school of social work accredited by the Council on Social Work Education; or (2) Has served for at least two years as a social worker, one year of which was in a dialysis unit or transplantation program prior to September 1, 1976, and has established a consultative relationship with a social worker who qualifies under paragraph (1) of this definition. The social worker may be an employee of the facility or be in a contractual relationship with the facility. (Refer also to the Interpretive Guidelines at §405.2163(c).) For any patient considered for self-dialysis or home dialysis, there should be a thorough psychosocial evaluation which was performed prior to the initiation of training. Survey Procedures and Probes: §405.2137(a)(1) Ask patients what choice of treatment modalities (transplantation, hemodialysis, peritoneal dialysis, home dialysis, self-help, etc.) were given them. How did they decide on the treatment modality they are now using? How often are they asked to participate in reviews of their program? Ask patients who discussed the option of transplantation with them. What risks and benefits of transplantation were they told about? Review the patient's long term plan and discuss it with the patient. How does the patient's plan reflect his/her desires with respect to the current treatment modality? How has the staff tried to accommodate the long-term plan to the patient's needs or desires?

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V189	(2) The program is formally reviewed and revised in writing as necessary by a team which includes but is not limited to the physician director of the dialysis facility or center where the patient is presently being treated, in addition to the other personnel listed in paragraph (a)(1) of this section at least every 12 months or more often as indicated by the patient's response to treatment (see §405.2161(b)(1) and §405.2170(a).	§405.2137(a)(2)
V190	(3) The patient, parent, or legal guardian, as appropriate, is involved in the development of the patient's long-term program, and due consideration is given to his preferences.	Survey Procedures and Probes: §405.2137(a)(3) Interview patients to find out if someone talked to them about their suitability for transplantation or other modalities. Who explained the modalities? What did they say?
V191	(4) A copy of the patient's long-term program accompanies the patient on interfacility transfer or is sent within 1 working day.	Interpretive Guidelines: §405.2137(a)(4) Acute care hospitals are not required to complete the long-term program.
V192	(b) Standard: Patient care plan. There is a written patient care plan for each patient of an ESRD facility (including home dialysis patients under the supervision of the ESRD facility; see §405.2163(e)), based upon the nature of the patient's illness, the treatment prescribed, and an assessment of the patient's needs.	Interpretive Guidelines: §405.2137(b) Under the aegis of the statement that an individualized written patient care plan is based upon ". . . treatment prescribed, and an assessment of the patient's needs," you can analyze the "adequacy" of dialysis treatments.

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V193	(1) The patient care plan is personalized for the individual, reflects the psychological, social, and functional needs of the patient, and indicates the ESRD and other care required as well as the individualized modifications in approach necessary to achieve the long-term and short term goals.	Interpretive Guidelines: §405.2137(b)(1) The patient care plan ensures that the patient receives individualized care within the selected modality of treatment. If all patients have the same dialysis prescription, e.g., using the same type dialyzer for 3 hours at a 250 blood flow rate, or the same diet, e.g., 60 gm PRO, 2 gm Na, 2 gm K+, the care is not individualized. Survey Procedures and Probes: §405.2137(b)(1) What evidence is there that the patient's medical, dietary, psychosocial, and rehabilitation needs are being met? Is the dialysis prescription individualized for each patient? Is the dietary prescription individualized for each patient? Find out if patients are aware of their unique clinical problem areas and the behaviors related to these clinical areas. Questions may include the following: What things do you need to be careful about because of your renal disease and treatment? What do you do to manage these areas of your health?
V194	(2) The plan is developed by a professional team consisting of at least the physician responsible for the patient's ESRD care, a qualified nurse responsible for nursing services, a qualified social worker, and a qualified dietitian.	§405.2137(b)(2)
V195	(3) The patient, parent, or legal guardian, as appropriate, is involved in the development of the care plan, and due consideration is given to his preferences.	§405.2137(b)(3)

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V196	(4) The care plan for patients whose medical condition has not become stabilized is reviewed at least monthly by the professional patient care team described in paragraph (b)(2) of this section. For patients whose condition has become stabilized, the care plan is reviewed every 6 months. The care plan is revised as necessary to insure that it provides for the patients' ongoing needs.	§405.2137(b)(4)
V197	(5) If the patient is transferred to another facility, the care plan is sent with the patient or within 1 working day.	§405.2137(b)(5)
V198	(6) For a home-dialysis patient whose care is under the supervision of the ESRD facility, the care plan provides for periodic monitoring of the patient's home adaptation, including provisions for visits to the home by qualified facility personnel to the extent appropriate. (See §405.2163(e)).	Interpretive Guidelines: §405.2137(b)(6) The care plan for patients on home dialysis should reflect conditions specific to the home dialysis environment. See also §405.2163(e). Survey Procedures and Probes: §405.2137(b)(6) Interview selected home patients. Due to time limitations and/or budget constraints, this may be done by telephone. Ask home patients how their home equipment is maintained? How is the water used in the preparation of dialysate monitored?

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V199	(7) Beginning July 1, 1991, for a home dialysis patient, and beginning January 1, 1994, for any dialysis patient who uses EPO in the home, the plan must provide for monitoring home use of EPO that includes the following: (i) Review of diet and fluid intake for indiscretions as indicated by hyperkalemia and elevated blood pressure secondary to volume overload.	Interpretive Guidelines: §405.2137(b)(7) The care plan must include provisions for adequate monitoring of the home patient's condition (refer to §405.2163(e)) that could be affected by Epoetin alfa (referred to as "EPO" in the regulations). Survey Procedures and Probes: §405.2137(b)(7) Review records of dialysis patients for whom EPO is prescribed at home. What indication is there that the care plan has provisions for regular monitoring of the patients' blood chemistries, especially iron and potassium? There should also be provisions for the patients' blood pressure to be monitored. If a patient is unable to give himself/herself the drug, assure that the patient has an adequate care-giver who can administer EPO. Ask patients what problems, if any, have they had since being on EPO. How do they monitor their blood pressure? How do they communicate with the health care staff about EPO and its effects?
V200	(ii) Review of medications to ensure adequate provision of supplemental iron.	§405.2137(b)(7)(ii)
V201	(iii) Ongoing evaluations of hematocrit and iron stores.	§405.2137(b)(7)(iii)

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V202	(iv) A reevaluation of the dialysis prescription taking into account the patient's increased appetite and red blood cell volume.	§405.2137(b)(7)(iv)
V203	(v) A method for physician followup on blood tests and a mechanism (such as a patient log) for keeping the physician informed of the results.	Interpretive Guidelines: §405.2137(b)(7)(v) The care plan must include a procedure for assuring that the physician is informed of the results of the blood tests. Survey Procedures and Probes: §405.2137(b)(7)(v) Review records of home dialysis patients who are prescribed EPO. There should be an indication (e.g., the physician's signature in the patient's chart) that the physician reviewed the blood test results and acted upon them.
V204	(vi)Training of the patient to identify the signs and symptoms of hypotension and hypertension.	Survey Procedures and Probes: §405.2137(b)(7)(vi) How is the patient taught to recognize the signs and symptoms of hypotension and hypertension? Are patients trained to take their own blood pressure?
V205	(vii) The decrease or discontinuance of EPO if hypertension is uncontrollable.	§405.2137(b)(7)(vii)

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
V215	§405.2138 Condition: Patients' rights and responsibilities. The governing body of the ESRD facility adopts written policies regarding the rights and responsibilities of patients and, through the chief executive officer, is responsible for development of, and adherence to, procedures implementing such policies. These policies and procedures are made available to patients and any guardians, next of kin, sponsoring agency(ies), representative payees (selected pursuant to section 205(j) of the Social Security Act and subpart Q of 20 CFR part 404), and to the public.	§405.2138
V216	The staff of the facility is trained and involved in the execution of such policies and procedures.	§405.2138
V217	The patients' rights policies and procedures ensure at least the following: (a) Standard: Informed patients. All patients in the facility: (1) Are fully informed of these rights and responsibilities, and of all the rules and regulations governing patient conduct and responsibilities;	Interpretive Guidelines: §405.2138(a)(1) "Fully informed" means that the facility has conscientiously tried, within the constraints of the individual situation, to inform the patient of the policies of the facility. There should be an indication in the patient's record that the patient (or parent, in the case of a child), guardians, next of kin, etc., received the information.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
V218	(2) Are fully informed of services available in the facility and of related charges including any charges for services not covered under title XVIII of the Social Security Act;	§405.2138(a)(2)
V219	(3) Are fully informed by a physician of their medical condition unless medically contraindicated (as documented in their medical records);	§405.2138(a)(3)
V220	(4) Are fully informed regarding the facility's reuse of dialysis supplies, including hemodialyzers. If printed materials such as brochures are utilized to describe a facility and its services, they must contain a statement with respect to reuse; and	Interpretive Guidelines: §405.2138(a)(4) To be fully informed the patient should understand (1) whether the facility practices reuse and, if so, what supplies are reused; and (2) the risks and benefits associated with this practice. Survey Procedures and Probes: §405.2138(a)(4) How does the facility inform patients about reuse practices?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
V221	(5) Are fully informed regarding their suitability for transplantation and home dialysis.	Survey Procedures and Probes: §405.2138(a)(5) There should be evidence in the record to indicate that patients were informed about their suitability for transplantation. Ask patients what they were told about transplantation. Ask patients what they were told about home dialysis.
V222	(b) Standard: Participation in planning. All patients treated in the facility: (1) Are afforded the opportunity to participate in the planning of their medical treatment and to refuse to participate in experimental research;	Interpretive Guidelines: §405.2138(b)(1) See also §405.2137 (b)(3) regarding patient participation in planning. Participation by a facility in experimental research must be approved by an institutional review board (IRB). An IRB is a federally administrated body of at least five members with backgrounds to promote complete and adequate review of research activities commonly conducted by an institution. Any institution engaged in research involving human subjects that is supported by a department or agency to which Federal policy applies, is subject to IRB oversight for review and approval of that research. (See 45 CFR 46). A patient being considered for participation in experimental research must be fully informed of the nature of the experiment (e.g., medication, treatment) and understand the possible consequences of participating. The patient's or his/her legal representative's written consent must be received prior to participation. Experimental research must respect the privacy of the patient. Any direct observation or use of patient-specific data requires the patient's (or guardian's) consent. Aggregated patient statistics that do not identify the individual patient may be used for studies without obtaining the patient's consent. Survey Procedures and Probes: §405.2138(b)(1) If research is conducted in this facility, how is it handled? What indication is there that patients are involved in the planning process?
V223	(2) Are transferred or discharged only for medical reasons or for the patient's welfare or that of other patients, or for nonpayment of fees (except as prohibited by title XVIII of the Social Security Act), and are given advance notice to ensure orderly transfer or discharge.	Interpretive Guidelines: §405.2138(b)(2) If the records show that any patient was discharged or transferred against his/her will, the reasons and steps taken to resolve problems before discharge should be discussed in the records. Survey Procedures and Probes: §405.2138(b)(2) What evidence is there to indicate that discharges or transfers of patients have been carried out in accordance with §405.2138(b)(2)? What evidence is there to indicate that advance notice was given to patients before transfer?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
V224	(c) Standard: Respect and dignity. All patients are treated with consideration, respect, and full recognition of their individuality and personal needs, including the need for privacy in treatment.	Survey Procedures and Probes: §405.2138(c) Observe interactions in the patient treatment area. Are patients exposed without screens? Are patients treated with dignity? Ask patients if they feel that the staff demonstrates a sensitivity to patient respect and privacy. Ask patients if they feel that the staff could do anything to provide them with more respect and more privacy during their treatment? If yes, ask what would they suggest.
V225	Provision is made for translators where a significant number of patients exhibit language barriers.	Survey Procedures and Probes: §405.2138(c) What provisions are made for cultural diversity within the facility?
V226	(d) Standard: Confidentiality. All patients are ensured confidential treatment of their personal and medical records, and may approve or refuse release of such records to any individual outside the facility, except in case of their transfer to another health care institution or as required by Federal, State, or local law and the Secretary for proper administration of the program.	Survey Procedures and Probes: §405.2138(d) How does the facility ensure the confidentiality of patients' records?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
V227	(e) Standard: Grievance mechanism. All patients are encouraged and assisted to understand and exercise their rights. Grievances and recommended changes in policies and services may be addressed to facility staff, administration, the network organization, and agencies or regulatory bodies with jurisdiction over the facility, through any representative of the patient's choice, without restraint or interference, and without fear of discrimination or reprisal.	Interpretive Guidelines: §405.2138(e) The facility's policies and procedures should describe grievance procedures available to the patient. The patient can file a grievance with the facility, the network organization, and/or the State agency. Survey Procedures and Probes: §405.2138(e) Ask to review the grievance file. What evidence is there that patients are aware of the various grievance mechanisms available? Ask patients if they know about the facility's grievance mechanism. If they had a problem at the facility who would they talk with? What would they do if the situation wasn't remedied? Do they know about the network's grievance mechanism? Have they or anyone they know needed to use the grievance mechanism? What happened? Do they know about the State agency's grievance mechanism?
V230	§405.2139 Condition: Medical records. The ESRD facility maintains complete medical records on all patients (including self-dialysis patients within the self-dialysis unit and home dialysis patients whose care is under the supervision of the facility) in accordance with accepted professional standards and practices. A member of the facility's staff is designated to serve as supervisor of medical records services, and ensures that all records are properly documented, completed, and preserved. The medical records are completely and accurately documented, readily available, and systematically organized to facilitate the compilation and retrieval of information.	Interpretive Guidelines: §405.2139 The medical record serves as a basis for documentation of health care rendered to the patient.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
V231	(a) Standard: Medical record. Each patient's medical record contains sufficient information to identify the patient clearly, to justify the diagnosis and treatment, and to document the results accurately.	Survey Procedures and Probes: §405.2139(a) If the patient is receiving parenteral nutrition, is there documentation of ongoing monitoring of the patient's nutritional status and response to parenteral nutrition?
V232	All medical records contain the following general categories of information: Documented evidence of assessment of the needs of the patient,	§405.2139(a)
V233	Whether the patient is treated with a reprocessed hemodialyzer,	Interpretive Guidelines: §405.2139(a) Survey this requirement in conjunction with §405.2150.
V234	Of establishment of an appropriate plan of treatment, and of the care and services provided (see §405.2137(a) and (b));	Interpretive Guidelines: §405.2139(a) §405.2137(a) and (b) refer to the patient long term plan and patient care plan.
V235	Evidence that the patient was informed of the results of the assessment described in §405.2138(a)(5);	Survey Procedures and Probes: §405.2139(a) Is there evidence documented in the medical record that the patient was informed of his/her suitability for transplantation and home dialysis?
V236	Identification and social data;	§405.2139(a)

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
V237	Signed consent forms, referral information with authentication of diagnosis;	Interpretive Guidelines: §405.2139(a) A "signed consent form" may: o Authorize a facility or physician to perform designated procedures; o Authorize a facility to release certain information to designated person(s) or facility(ies); or o Signify that the patient understands that the facility reuses dialyzers.
V238	Medical and nursing history of patient;	Interpretive Guidelines: §405.2139(a) You may see copies of histories and physicals (H&P) from hospital admissions being used as the H&P in the record. If this is the practice, the content should address the renal disease aspects of the patient's medical history. Survey Procedures: §405.2139(a) Recommend the H&P be updated annually at a minimum. Ask the responsible nurse where the nursing history of the patient is documented. Review these as part of your record review.
V239	Report(s) of physician examination(s);	§405.2139(a)
V240	Diagnostic and therapeutic orders;	§405.2139(a)
V241	Observations and progress notes;	Interpretive Guidelines: §405.2139(a) Dialysis flow sheets are the primary means of documenting the daily care of dialysis patients. These treatment summaries consist of information, such as a vital signs, weight, laboratory tests, x-ray findings, medications given, clotting time, reports of fluid intake and output, and other treatment related parameters such as target weight, blood flow rate and documentation of testing for machine parameters such as pH and conductivity.
V242	Reports of treatments and clinical findings;	§405.2139(a)

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
V243	Reports of laboratory and other diagnostic tests and procedures; and	§405.2139(a)
V244	Discharge summary including final diagnosis and prognosis.	Interpretive Guidelines: §405.2139(a) Expect to find discharge summaries from the dialysis facility only if a patient expires, is transferred, or is transplanted and is no longer followed by the medical staff of the facility. Medical staff by-laws or facility policy should define a timeline for completion of these summaries. Content should include the disposition of the patient.
V245	(b) Standard: Protection of medical record information. The ESRD facility safeguards medical record information against loss, destruction, or unauthorized use. The ESRD facility has written policies and procedures which govern the use and release of information contained in medical records. Written consent of the patient, or of an authorized person acting in behalf of the patient, is required for release of information not provided by law. Medical records are made available under stipulation of confidentiality for inspection by authorized agents of the Secretary, as required for administration of the ESRD program under Medicare.	Survey Procedures and Probes: §405.2139(b) Where are closed records and thinned portions of open records stored? Is this area protected from casual access? Are requested records retrieved quickly?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
V246	(c) Standard: Medical records supervisor. A member of the ESRD facility's staff is designated to serve as supervisor of the facility's medical records service. The functions of the medical records supervisor include, but are not limited to, the following: Ensuring that the records are documented, completed, and maintained in accordance with accepted professional standards and practices; safeguarding the confidentiality of the records in accordance with established policy and legal requirements; ensuring that the records contain pertinent medical information and are filed for easy retrieval. When necessary, consultation is secured from a qualified medical record practitioner.	Interpretive Guidelines: §405.2139(c) A medical records supervisor may be or may seek consultation from a qualified medical records practitioner. A qualified medical record practitioner as defined in §405.2102 is a person who: (1) has graduated from a program for Medical Record Administrators accredited by the Council on Medical Education of the American Medical Association and the American Medical Record Association, and is eligible for certification as a Registered Record Administrator (RRA) by the American Medical Record Association under its requirements in effect on June 3, 1976; (2) has graduated from a program for Medical Record Technicians approved jointly by the Council on Medical Record Technicians approved jointly by the Council on Medical Education of the American Medical Association and the American Medical Record Association, and is eligible for certification as an Accredited Record Technician (ART) by the American Medical Record Association under its requirements in effect June 3, 1976; or (3) has successfully completed and received a satisfactory grade in the American Medical Record Association's Correspondence Course for Medical Record Personnel approved by the Accrediting Commission of the National Home Study Council, and is eligible for certification as an Accredited Record Technician by the American Medical Record Association under its requirements in effect June 3, 1976. Survey Procedures and Probes: §405.2139(c) Generally, facilities will not have a qualified medical records practitioner on their staff. You may see a contract/letter of agreement with a qualified medical records practitioner, but this is not required by regulation. If the outcome is that significant problems are identified with medical records, such consultation is "necessary" and should be cited here.
V247	(d) Standard: Completion of medical records and centralization of clinical information. Current medical records and those of discharged patients are completed promptly. All clinical information pertaining to a patient is centralized in the patient's medical record.	Interpretive Guidelines: §405.2139(d) In a dialysis unit, it is essential that each clinical event be documented as soon as possible after its occurrence. Documentation must be currently maintained so that flow sheets and other records provide an up-to-date evaluation of the status of the patient at all times. Survey in conjunction with §405.2163(e)(3).

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V248	Provision is made for collecting and including in the medical record medical information generated by self-dialysis patients. Entries concerning the daily dialysis process may either be completed by staff, or be completed by trained self-dialysis patients, trained home dialysis patients or trained assistants and countersigned by staff.	§405.2139(d)
V249	(e) Standard: retention and preservation of records. Medical records are retained for a period of time not less than that determined by the State statute governing records retention or statute of limitations; or in the absence of a State statute, 5 years from the date of discharge; or, in the case of a minor, 3 years after the patient becomes of age under State law, whichever is longest.	Interpretive Guidelines: §405.2139(e) The accumulation of records for a patient treated 2 to 3 times a week can become voluminous. It is therefore likely that the facility may choose to retain a record of the last several dialysis treatments and a current summary in the unit, with the older records stored in a convenient safe location. Storage in computer files is permissible only if a means to protect the integrity of the records is provided. Authentication may be provided by a signature, initial, or unique identification number. Survey Procedures and Probes: §405.2139(e) If records are computer-generated, ask the records supervisor to explain the procedure which ensures safeguarding the records against loss and alteration. How are the records authenticated?
V250	(f) Standard: location and facilities. The facility maintains adequate facilities, equipment, and space conveniently located, to provide efficient processing of medical records (e.g., reviewing, filing, and prompt retrieval) and statistical medical information (e.g., required abstracts, reports, etc.).	Survey Procedures and Probes: §405.2139(f) Ask to see where records are stored. Ask how records are protected from damage and casual access.

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V251	(g) Standard: Transfer of medical information. The facility provides for the interchange of medical and other information necessary or useful in the care and treatment of patients transferred between treating facilities, or in determining whether such patients can be adequately cared for otherwise than in either of such facilities.	Interpretive Guidelines: §405.2139(g) The facility must have established policies and procedures for the prompt transfer of medical information between treatment facilities. The intent is to make the transfer of patient information between facilities as easy as possible so that continuity of care can be provided whenever patients have to leave the community temporarily (e.g., vacation, business, hospitalization), or transfer permanently to a new facility. Survey Procedures and Probes: §405.2139(g) Ask the records supervisor what procedures are followed to facilitate the transfer of patient medical information to another facility.
V255	§405.2140 Condition: Physical environment The physical environment in which ESRD services are furnished affords a functional, sanitary, safe, and comfortable setting for patients, staff and the public.	§405.2140
V256	(a) Standard: Building and equipment. The physical structure in which the ESRD services are furnished is constructed, equipped, and maintained to insure the safety of the patients, staff, and the public.	Interpretive Guidelines: §410.2140(a) The facility should be located in a building that can accommodate the needs of patients who may be disabled. All equipment needed for the comfort and safety of patients and staff (air conditioners, heat, exhaust fans, smoke detectors, etc.) should be in good working order or under repair.

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V257	(1) Fire extinguishers are conveniently located on each floor of the facility and in areas of special hazard. Fire regulations and fire management procedures are prominently posted and properly followed.	Interpretive Guidelines: §405.2140(a)(1) Fire extinguishers should be supplied in accordance with State and local fire regulations and there should be a sufficient number for the size of the facility. Their locations should be marked on the floor plan and staff and patients should be trained in their operation. Procedures for emergency evacuation of the building should be posted and the staff and patients should be trained in their execution. A floor plan with clearly marked exit routes should also be prominently posted throughout the unit. Survey Procedures and Probes: §405.2140(a)(1) Look for evidence (e.g., a dated tag on the extinguisher) that fire extinguishers are regularly inspected and maintained. What evidence is there to indicate that the staff and patients have been trained in the operation of the fire extinguisher?
V258	(2) All electrical and other equipment used in the facility is maintained free of defects which could be a potential hazard to patients and personnel. There is established a planned program of preventive maintenance of equipment used in dialysis and related procedures in the facility.	Interpretive Guidelines: §405.2140(a)(2) Electrical equipment includes, but is not limited to, items such as dialysis delivery systems (including all components such as the blood pump, infusion device, air detector, etc.), crash cart, ECG and defibrillator, electric scales, reprocessing equipment (automated as well as any electrical components of manual systems). All electrical equipment should have the proper grounding connections to meet State and local regulations. Tests for electrical leakage should be performed and documented. Equipment under repair should be removed from the treatment areas or if that is not possible, should be tagged to indicate that it is undergoing repair. Any device undergoing repair should be tagged to indicate that it is undergoing repair. Devices undergoing repair should not be used by patients or staff unless precautions are made to protect them from exposure to electrical hazards. Repair of equipment should be performed by manufacturers' representatives or persons whose personnel records indicate they are qualified by training or experience to service the particular equipment. Preventive maintenance should be conducted by qualified technicians according to a schedule recommended by the manufacturer of the equipment, or according to a plan developed by the facility.

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		Interpretive Guidelines: §405.2140(a)(2) - (Cont.)-- The following machine functions should be calibrated periodically (or as specified by the manufacturer or the facility): blood pump, air bubble detector/line clamp, blood leak detector, audio/visual alarms, temperature, conductivity and pH, negative pressure/ultrafiltration pump, arterial pressure monitor, and venous pressure monitor. Scales should be calibrated regularly. Internal transducer protectors should be changed during the maintenance procedures. If there have been any deaths or serious injuries caused by equipment or maintenance problems, the facility should have reported this to the manufacturer and/or the FDA as appropriate, and taken steps to prevent similar occurrences from happening in the future. If you think that the facility is not in compliance with FDA regulations, contact the HCFA RO. Survey Procedures and Probes: §405.2140(a)(2) Review maintenance records. They should include documentation of safety checks performed in accordance with intervals recommended by the manufacturer or the facility. Documentation of maintenance on each dialysis machine should be current and complete.
V259	(3) The areas used by patients are maintained in good repair and kept free of hazards such as those created by damaged or defective parts of the building.	Survey Procedures and Probes: §405.2140(a)(3) During your inspection, be alert for broken floor tiles, damaged ceiling tiles, water spills, etc.
V260	(4) [Reserved]	

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
V261	(5)(i) The ESRD facility must employ the water quality requirements listed in paragraph (a)(5)(ii) of this section developed by the Association for the Advancement of Medical Instrumentation (AAMI) and published in "Hemodialysis Systems," second edition, which is incorporated by reference. (ii) Required water quality requirements are those listed in sections 3.2.1, Water Bacteriology; 3.2.2 Maximum Level of Chemical Contaminants; and in Appendix B: Guideline for Monitoring Purity of Water Used for Hemodialysis as B1 through B5. (iii) Incorporation by reference of the AAMI's "Hemodialysis Systems," second edition, 1992, was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. If any changes in "Hemodialysis Systems," second edition, are also to be incorporated by reference, a notice to that effect will be published in the Federal Register.	Interpretive Guidelines: §405.2140(a)(5) Water used for dialysis purposes must be analyzed periodically and treated as necessary to maintain a continuous water supply that is biologically and chemically compatible with acceptable dialysis techniques. Records of test results and equipment maintenance are maintained at the facility. Most professionals in this field have recognized that adherence to water quality standards developed by the Association for the Advancement of Medical Instrumentation (AAMI) can provide safe water for the preparation of dialysate. These standards not only include recognition of professionally accepted maximum levels of contaminants in the treated water, but also include professionally accepted methods for achieving those levels, including the proper selection, use of equipment, training, and education of the personnel performing these operations. The type of water treatment equipment that may be necessary for a particular facility will depend on the source water and the level of contaminants that normally can be anticipated from that source. The equipment should be operated and serviced by trained personnel experienced in the operation of the particular system. A written protocol describing how the system is to be operated and maintained should be included in the records of the facility. The policies and procedures for the operation of the water treatment system should address the safe and effective operation of the system and should include, but not necessarily be limited to, such topics as: basic operation and use of the system, preventive maintenance procedures and schedules, cleaning and disinfection procedures, calibration of measurement and monitoring instruments, trouble shooting and repair. The medical director should verify that the individual responsible for operation of the water treatment system has had the necessary experience and training prior to employment ,or that the individual has successfully completed an educational and training program established by the facility. The medical director should also verify that the water treatment technician's performance in carrying out the requirements of his/her job is evaluated periodically. If this requirement if not met, cite at V144.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
V26201-98	**AAMI Requirement as Adopted by Reference 42 CFR 405. 2140(a)(5)(ii)** 3.2.1 **Water Bacteriology** 3.2.1.1 **Water Used to Prepare Dialysate**. Total viable microbial counts should not exceed 200/ml. A method of cleaning the equipment so that the equipment is capable of meeting this requirement shall be recommended by the manufacturer or supplier. Monitoring of the water bacteriology of the system following installation is the responsibility of the user (see Appendix B). The AAMI requirements listed above are those referenced at 42 CFR 405.2140(a)(5)(ii) and are regulatory.	Survey Procedures and Probes: §405.2140(a)(5) The level of microbial contamination in dialysate water should not exceed 200 CFU/ml for bacteria and have no more than five endotoxin units (EU)/ml. The current AAMI standards give the user a choice of doing either a test for bacterial colony count or a test for endotoxin, or both. There can be instances where bacterial counts may be well within the standards, but endotoxin may be elevated. The bacterial levels in water should be evaluated at least monthly and after any suspected pyrogenic reactions or any modifications made to the water treatment/distribution systems or disinfection protocols. Water samples should be taken to determine the worst possible level of contamination, i.e., testing should be done just before disinfection is done, preferably from a stagnant site. Review water culture results. They should be quantitative. Ask what culture techniques are used. Pour plate, spread plate, or membrane filter technique should be used. Typically a system which allows cultures to be taken, incubated and read in the facility is used. Samples should be cultured within 30 minutes or refrigerated at 4□C and tested within 24 hours of collection. Trypticase soy agar (TSA) is the culture medium of choice. Colonies should be counted after 48 hours of incubation at 35-37□C. The finding of "no growth" for months would be questioned - sterile water is not being produced; some growth is expected. If cultures are sent to a laboratory, are specimens properly labeled as "water" or "dialysate"? Have facility staff talked with the laboratory to assure appropriate culture methods are used, i.e., a calibrated loop should not be used (because these loops sample small volumes and are inaccurate)?

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		Samples for endotoxin testing should be collected in endotoxin-free tubes and tested as soon as possible. Samples can be assayed using the Bacterial Pyrogen Test (Gel-clot) or equivalent method that uses the Limulus amebocyte lysate (LAL). If samples cannot be tested immediately, they should be handled as noted above. Endotoxin is the agent responsible for pyrogenic reaction in hemodialysis patients. Outbreaks of pyrogenic reactions and bacteremia have been linked to bacterial reservoir in hemodialysis systems and to water containing organisms in excess of AAMI standards.
V263	**AAMI Requirement as Adopted by Reference 42 CFR 405. 2140(a)(5)(ii)** 3.2.1.2 **Bacteriology of the Dialysate**. Total viable microbial count for the dialysate should not exceed 2000/ml. The supplier of the dialysate supply system shall be responsible for recommending a method of cleaning the equipment that will result in a device capable of meeting the requirements of this section. The user is responsible for monitoring the purity of the dialysate (see Appendix B).	Survey Procedures and Probes: §405.2140(a)(5)(ii) Review dialysate culture results. Bacteriological testing of the dialysate should be performed and the results documented. The bacteria level in dialysate should be evaluated at least monthly.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		AAMI Rationale for the Development and Provision of this Recommended Practice *Note: AAMI-developed rationale for their recommended practice for water for hemodialysis is included in the guidance to surveyors for ease of reference.* (3.2.1.2) Bacteriology of the Dialysate - The supplier of water treatment equipment is responsible for recommending a method of cleaning the equipment that can routinely produce water meeting the bacteriology requirements of this standard when typical feed water is presented. Beyond this qualification, it becomes the responsibility of the user of the system to monitor the system for ongoing compliance with the standard. User responsibilities are addressed in Appendix B (refer to Appendix B which follows). Several groups of investigators have shown convincingly that pyrogenic reactions are caused by lipopolysaccharide or endotoxin that is associated with gram-negative bacteria. Furthermore, gram-negative water bacteria have been shown to have the capability of multiplying rapidly in a variety of hospital-associated fluids, including distilled, deionized, reverse osmosis, and softened water, all of which can be used as supply water for hemodialysis systems. The dialysate, which is a balanced salt solution made with this water, likewise provides a very good growth medium for these types of bacteria. The use of "high flux" open membranes has raised the possibility of a greater likelihood of passage of endotoxins or organisms into the blood path. That has not been documented to occur, but use of such membranes should be accompanied by greater awareness of the need for high-quality water treatment and cautious monitoring of water, concentrate, dialysate, and fluid paths. Excessive levels of gram-negative water bacteria in the dialysate of artificial kidney machines have been shown to be responsible for pyrogenic reactions, sepsis, or both. In addition, it has been shown that problems relating to microbial contamination in dialysis systems do not usually have a single cause, but rather are the result of a number of causes and factors involving the water treatment system, the water and dialysate distribution systems, and in some cases, the type of hemodialyzer. The key to preventing high levels of microbial contamination is understanding the various factors and their influence on contamination levels. Neither the water used to prepare dialysate nor the dialysate itself needs to be sterile. Microbial contamination, however, should be maintained at a low level. Epidemiologic studies by several investigators have shown that if counts in water used to prepare dialysate exceed 200 bacteria per ml, a potential problem exists, because these concentrations can be amplified in other parts of the system, resulting in a high level of bacteria in the dialysate. Furthermore, epidemiologic evidence has shown that if the level of contamination exceeds 2000 bacteria per ml in the dialysate, there can be an increased risk of pyrogenic and septicemic complications.

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		AAMI Rationale for the Development and Provision of this Recommended Practice (3.2.1.2) Bacteriology of the Dialysate continued - Conversely, pyrogenic reactions do not appear to occur when the level of contamination is below 2000 bacteria per ml in dialysate, unless the source of the endotoxin is exogenous to the dialysis system (i.e., present in the community water supply). That pyrogenic reactions can be caused by endotoxins in a community water supply has been further demonstrated by Hindman et. al. (1975). It is clear that the elimination of both high levels of gram-negative bacteria in dialysate and accompanying high concentrations of endotoxin (the internal source of endotoxin), coupled with the use of reverse osmosis water treatment, which has been shown to remove endotoxin from water used to prepare dialysate (external source), can virtually eliminate risk of pyrogenic reactions in dialysis patients. Several investigators (Jones et al. 1970; Kidd 1964) have shown that bacteria growing in dialysate produced products that could cross the dialysis membrane. It has also been shown (Gazenfeldt-Gazit & Eliahou 1969; Raji et al. 1973) that gram-negative bacteria growing in dialysate produced endotoxins that in turn stimulated the production of antiendotoxin in dialyzing patients. This suggests that bacterial endotoxins, although relatively large molecules, do indeed cross dialysis membranes. The discrepancy between these studies is unexplained. Nevertheless, several studies have demonstrated that the attack rates of pyrogenic reactions are related directly to the number of bacteria in dialysate (Dawids & Vejlsgaard 1976; Favero et al. 1974; Favero et al. 1975). These studies provide the rationale for setting the guidelines at about 2000 bacteria per ml in dialysate and at about 200 bacteria per ml for the water used to prepare dialysate. In the latter case, it is known that the level of contamination exceeds 200 bacteria per ml in water, this level can be amplified in the system and effectively constitute a high inoculum for dialysate at the start of a dialysis treatment. Furthermore, the level of microbial contamination in many dialysis systems constantly increases from the start of the dialysis treatment. This is especially true in recirculating single-pass systems; a concentration of over 2000 bacteria per ml at the start of a treatment will predictably reach 10^6 per ml and quite often 10^7 to 10^8 per ml after 5 hours of dialysis.

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V264	**AAMI Requirement as Adopted by Reference 42 CFR 405. 2140(a)(5)(ii)** 3.2.2 **Maximum Level of Chemical Contaminants.** The water used to prepare dialysate shall not contain chemical contaminants at concentrations in excess of those in Table 2. The manufacturer or supplier of the water treatment device shall recommend a system capable of meeting the requirements of this section. The physician in charge of dialysis has the ultimate responsibility for selecting the water treatment system and is also responsible for monitoring the water (see Appendix B). Note: For ease in formatting, the applicable parts of Appendix B incorporated by these regulations are reprinted in these interpretive guidelines beginning in the next column. Note that Appendix B of the AAMI standards is specifically referenced at 42 CFR 405.2140(a)(5)(ii) and is regulatory.	**Appendix B - 1993 Association for the Advancement of Medical Instrumentation "Hemodialysis Systems"** **Guideline for Monitoring Purity of Water Used for Hemodialysis; Criteria for Selection of Water Treatment Equipment; General Guidelines for the User** **B1. Introduction** - The Renal Disease and Detoxification Committee of the Association for the Advancement of Medical Instrumentation prepared this guideline with the intention of outlining what it considered to be the responsibilities of users of hemodialysis systems to ensure the purity of the water used for hemodialysis. This guideline is offered as an appendix to the standard because it is addressed to the user (physician or medial professional designated by the physician) of the medical device, rather than to the manufacturer of the device. Certain of the committee's recommendations apply to both the manufacturer and to the user, and these are presented both in the body of the standard and in the appendix. Although this may seem an unnecessary duplication of information, the committee felt that this format would clarify the delineation of responsibility. **B2. Applicability of the Guideline** - This guideline is not intended to apply in every case or to be achievable in all situations. Rather, the recommendations contained herein are meant to be goals moderated by individual circumstances and by judgement of the managing physician. In addition, this guideline is not meant to take the place of existing federal regulations and laws. On the contrary, this guideline is intended to supplement those regulations and laws which, while not enumerated here, should be part of the user's program of assuring water purity. **B3. Need for this Guideline** - Contaminants in water used to make dialysate may cause adverse reactions by entering the patient's blood stream through the membrane of the hemodialyzer. Some chemical contaminants have been reported to be toxic in humans when present above certain trace levels in drinking water, but have not yet been shown to cause adverse reactions when used in water for dialysis. Still other chemical contaminants are normally not harmful as present in usual physiological fluids, but they can become dangerous if their concentrations are increased by contaminants in the water used to make dialysate. Organic chemical contaminants and radioactive contaminants have not been addressed, except in terms of recommended water treatment methods, due to lack of conclusive evidence of their toxicity. Limits on bacterial growth in the dialysate are necessary to prevent high bacterial counts which have been associated in the past with pyrogenic reactions.

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	AAMI Requirement as Adopted by Reference 42 CFR 405. 2140(a)(5)(ii) **Table 2 - Hemodialysis Water Quality: Maximum Allowable Chemical Contaminant Levels*** Contaminant — Suggested Maximum Level (mg/l) Calcium — 2 (0.1 mEq/l) Magnesium — 4 (0.3 mEq/l) Sodium** — 70 (3.0 mEq/l) Potassium — 8 (0.2 mEq/l) Fluoride — 0.2 Chlorine (free) — 0.5 Chloramine — 0.1 Nitrate (N) — 2.0 Sulfate — 100.0 Copper, Barium, Zinc — each 0.1 Aluminum — 0.01 Arsenic, Lead, Silver — each 0.005 Cadmium — 0.001 Chromium — 0.014 Selenium — 0.09 Mercury — 0.0002 *The physician has the ultimate responsibility for assuring the quality of water used for dialysis (see Section 3.2.2 and Appendix B) **230 mg/l (10 mEq/l) where sodium concentration has been reduced to compensate for the excess sodium in the water, as long as conductivity of the water is being continually monitored.	**Appendix B - 1993 Association for the Advancement of Medical Instrumentation "Hemodialysis Systems" - continued** **Guideline for Monitoring Purity of Water Used for Hemodialysis; Criteria for Selection of Water Treatment Equipment; General Guidelines for the User** **B4. Purpose of the Guideline** - While the selection of the purity level of water used for dialysis is ultimately the responsibility of the physician, recommended levels for many contaminants have been clearly defined and supported by the scientific literature. There is, however, still discussion about the need to treat water for dialysis, the type of water treatment device(s) to use, and the frequency with which the water should be monitored. The purpose of this appendix, then, is to delineate committee recommendations with respect to these issues as they apply to the user of the device. Recommendations made by such groups as the American Public Health Association, the Office of the Surgeon General of the United States, and the Canadian Bureau of Medical Devices have reinforced the opinion of the committee that many of the responsibilities of assuring water purity are rightly within the purview of the user of the device rather than the manufacturer or supplier of the device. One of the purposes of this guideline, then, is to provide some practical guidance for the user in fulfilling his or her responsibilities in this regard. **B5. Frequency of Monitoring** - Monitoring of water purity levels is considered the sole responsibility of the physician in charge of dialysis or the medical professional designated by the physician as the person in charge. The manufacturer or supplier of the water treatment equipment is expected to ensure the level of purity demanded by the standard or specified by the physician at the time of initial qualification and installation of the equipment. Beyond this initial qualification, it becomes the responsibility of the managing physician, or his or her designee, to ensure that the quality of water is maintained at the desired level. Recommended maximum levels of contaminants are given in Section 3.2.1 and 3.2.2 of the standard. The bacteriology of water and dialysate should be sampled at least monthly or more frequently to define, solve, and control problems. Home patients are a possible exception to this monthly recommendation. The monthly interval is recommended because although bacterial levels can rise rapidly, this is an uncommon event and the risk of adverse reaction is low, and because monthly testing will detect correctable errors in technique. The frequency of sampling for maximum allowable levels of chemical contaminants in water varies with the method of water treatment. When reverse-osmosis or deionization devices are used, testing should be done at least every 12 months. When a method other than deionization, reverse osmosis, or a comparable system is used, testing should be done at least every 3 months and at times of expected high levels of contamination. The chemical contaminants in water may vary widely from month to month. In addition, water treatment systems and monitoring systems can fail and, even in the best circumstances, cannot necessarily account for all possible fluctuations in the feed water supply. Hence, monthly testing is recommended initially. These results can be kept as a log of the particular facility and can be used to determine the optimum frequency of testing for that particular facility.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		Appendix B - 1993 Association for the Advancement of Medical Instrumentation "Hemodialysis Systems" - continued **Guideline for Monitoring Purity of Water Used for Hemodialysis; Criteria for Selection of Water Treatment Equipment; General Guidelines for the User** **B5. Frequency of Monitoring continued** - When chloramines are added municipally to the water supply, the water used to prepare dialysate should be checked for the presence of chloramines at least once each day. This practice can also reduce the cost of maintenance testing by identifying substances that are consistently within acceptable limits. These substances can then be tested less frequently. Frequent testing, at least initially, also provides a data base for determining times when high levels of contaminants may be expected. Maximum levels of organic chemicals, pesticides, herbicides, and radioactive materials cannot be specified at the present time. Frequency of testing, therefore, cannot be established. Reiterating the observation of the Canadian Bureau of Medical Devices in their report *Clinical Reverse Osmosis Units-Their Value and Their Limitations*, the committee suggested that the combination of a charcoal filter and reverse osmosis appears to be an effective method of filtering organic contaminants. The frequency of disinfection of the water treatment and disinfection system, dialysis machines, and equipment used to distribute and prepare dialysate should be determined by the results of microbiological monitoring, by any requirements to meet AAMI standards and/or guidelines, and by the manufacturers' recommendations. **AAMI Rationale for the Development and Provision of this Recommended Practice** (3.2.2) - Maximum Level of Chemical Contaminants. Contaminants identified as needing restriction on the allowable level which may be present in water for dialysis are divided into three groups for the purposes of this standard. The first group includes chemicals shown to cause toxicity in dialysis patients. These chemicals include fluoride, chloramine, sulfate, nitrate, zinc, copper, and aluminum. Chorine is included here because of its potential toxicity. Toxicity of fluoride in dialysis patients at the levels usually associated with fluoridated water - 1 part per million (ppm) - is questionable. In the absence of a consensus on its role in uremic bone disease, the committee initially thought it prudent to restrict the fluoride level of dialysate (Rao & Friedman 1975). Subsequently, illness in 8 of 8 dialysis patients, with the death of one patient, has been reported as a result of accidental overflouridation of a municipal water supply (CDC 1980). Levels of up to 50 ppm of fluoride were found in water used for dialysis which was treated only with a water softener. Probably these illnesses would have been less severe, if not prevented, if the dialysis water had been treated with deionization or reverse osmosis.

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		AAMI Rationale for the Development and Provision of this Recommended Practice (3.2.2) - Maximum Level of Chemical Contaminants continued - The suggested maximum aluminum level has been specified to prevent accumulation of this potentially toxic metal in the patient (Kovalchik et al. 1978). Aluminum is particularly likely to suddenly increase to high levels due to changes in the method of water treatment to include aluminum-containing compounds. As with fluoride, water treatment would provide a measure of safety should the aluminum levels increase dramatically between chemical tests of the product water. The toxicity of chloramine is undisputed (Eaton et al 1973). While the role of free chlorine in oxidative blood damage is unclear, its high oxidation potential and ability to form chloramines suggests the avoidance of highly chlorinated water in preparation of dialysate. Sulfate at levels above 200 mg/l has been related to nausea, vomiting, and metabolic acidosis. The symptoms disappear when the level remains below 100 mg/l (Comty et al. 1974). Nitrates are a marker for bacterial contamination and have caused methemoglobinemia (Carlson & Shapiro 1970) and should therefore be permitted only at very low levels. Both copper and zinc toxicity have been demonstrated when these substances are present in dialysate at levels below those permitted by the EPA standard (Ivonovich et al. 1969; Petrie & Row, 1977). Hence, a lower level has been chosen. The second group of chemical contaminants, based on the U.S. Environmental Protection Agency's *National Interim Primary Drinking Water Standard* (Applicable Document 2.3), includes barium, selenium, chromium, lead, silver, cadmium, mercury, and arsenic. Selenium and chromium levels are set at the "no transfer" level (Klein et al. 1979). The "no transfer" level was chosen even though it is above the EPA limit for selenium and 28 percent of the EPA limit for chromium, because there is no need for a restriction below the level at which there is no passage from the dialysate to the blood. The other maximum allowable limits in this group are specified in this standard at one-tenth of the EPA maximum allowable limits because the volume of water used for dialysis far exceed that used for drinking water, because protein binding may occur in the blood, and because there is reduced renal excretion of these substances. These reduced limits were selected using the following assumptions: (1) feed water entering dialysis systems typically meets the EPA *National Interim Primary Drinking Water Standard*; (2) typically, reverse osmosis treatment removes 90 to 99 percent of dissolved inorganic solids; and (3) reverse osmosis treated water is a suitable standard for safety of water used in dialysis.

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		AAMI Rationale for the Development and Provision of this Recommended Practice (3.2.2) - Maximum Level of Chemical Contaminants continued - These assumptions are based on the recommendations of Keshaviah et al. (1980). The committee recognized that these assumptions are questionable but reasoned that setting standards in this way will cause little or no economic impact, even though some feed water exceeds the EPA maximum allowable levels. It should be noted that the level for arsenic, 0.05 mg/l, in the Keshaviah report is a typographical error. The correct value is 0.005 mg/l as given in Table 1 of this standard (E. Klein, personal communication). The third group of substances addressed in 3.2.2 and Table 1 consists of physiological substances that can adversely affect the patient if present in the dialysate in excessive amounts. Calcium, potassium, and sodium are examples of these substances. Of the physiological substances that can be harmful when present in excessive amounts, the calcium level has been reduced from the 10 ppm originally selected to 2 ppm, based on the critical role of calcium in bone disorders associated with renal disease. A level of 10 ppm would have allowed a potential 20 percent error in dialysate calcium, whereas a 2 ppm level reduces that error risk to less than 5 percent. This requirement is expected to increase costs since many U.S. potable water supplies are high in calcium, and treatment, in addition to reverse osmosis, may be needed to meet the 2 ppm level. Nevertheless, the committee considered the margin of safety achieved by the more stringent requirement worthwhile, in view of the serious disease that may be caused by disturbances in calcium balance. With the exception of sodium in certain cases, higher levels of these physiological substances with the compensated dialysate concentrate are not recommended because of the instability of water sources with respect to these ions and the difficulty of continuously monitoring their levels. Table 1 of this standard should not be taken as a definitive list of harmful substances, but only a partial listing of those which might reasonably be expected to be present and have clinical implication. Iron is not included because it does not enter the patient's blood in sufficient quantities to cause toxicity. Iron may cause fouling of water purification devices (see Section 4.2.3.1) or dialysate supply systems. The Japanese standard for hemodialysis systems recommends a maximum level of iron of 0.3 mg/l. While the AAMI committee chose not to set a specific limit, water treatment equipment suppliers are encouraged to consider the iron content of the feed water when recommending suitable equipment. At this time, limits cannot be set for toxic organic substances or for radioactive materials (Keshaviah et al. 1980). However, the committee noted that the EPA drinking water standard (Applicable Document 2.3) lists the following maximum contaminant levels (mg/l) for toxic organic substances: Endrin-0.002; Lindane-0.004; Methoxychlor-0.1; and Tozaphane-0.005. Following the rationale used in establishing levels for other potentially toxic contaminants that have not been shown to be harmful to dialysis patients (see above), these levels should be reduced ten-fold if they are monitored.

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	End AAMI Guidelines	**AAMI Rationale for the Development and Provision of this Recommended Practice** (3.2.2) - Maximum Level of Chemical Contaminants continued - These data are provided for information purposes only, since these substances are but four of a vast number of contaminants that occur in tap water, all of whose toxic effects are largely unknown (Keshaviah et al. 1980). The committee also agreed with both the Keshaviah report and the Canadian Bureau of Medical Devices that systems including reverse osmosis and carbon filtration would adequately remove most organics. Interpretive Guidelines: §405.2140(a)(5)(ii) Water treatment systems must include a carbon tank and either a Reverse Osmosis or Deionization System. Some units use both. When chlorine/chloramines (sometimes called Total Chlorine) are added municipally to the water supply, the water used to prepare dialysate should be checked for the presence of these chemicals at least before treatments are begun each day. Even a short exposure to chlorine/chloramine can cause hemolysis. Survey Procedures and Probes: §405.2140(a)(5)(ii) The analysis of chemicals in water used for dialysis should be done at least annually. The water sample should be taken from where the treated water enters the distribution system. Review results of chemical analysis. Compare with AAMI allowable limits. Ask how the medical director is notified of water analysis results. What evidence is there that water is analyzed for bacterial and/or endotoxin contamination on a schedule that ensures that bacterial contamination of the water treatment system is maintained within established guidelines? What procedures have been developed to ensure that the system is periodically disinfected and flushed sufficiently after disinfection to reduce the concentration of residual disinfectant to safe levels? Examine the training requirements for water treatment personnel. The instructions should include, as a minimum, principles of dialysis and water treatment, patient complications that can result from improperly treated water, monitoring of equipment, calibration, interrelationships of each system component, the dialysate delivery system, dialysate, and dialyzer. Water treatment personnel should understand the importance of immediately reporting problems to the charge nurse and/or medical director.

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V265	(b) Standard: Favorable environment for patients. The facility is maintained and equipped to provide a functional, sanitary and comfortable environment with an adequate amount of well-lighted space for the service provided.	Interpretive Guidelines: §405.2140(b) "Sanitary environment" refers to infection control and prevention strategies. Because of the risk of nosocomial infection, an infectious and communicable diseases monitoring system should include an active surveillance program of specific measures for prevention, early detection, control, education, and investigation of infectious and communicable disease. There should also be a mechanism to evaluate the effectiveness of the program and take corrective action. The facility should institute the current recommendations of the Centers for Disease Control and Prevention (CDC) relative to the specific infection(s) and communicable disease(s). The facility may refer to the current references on infection control published by the CDC. Although not specifically mandated by HCFA regulations, facilities should follow the standard universal precautions promulgated by the CDC.
V266	(1) There are written policies and procedures in effect for preventing and controlling hepatitis and other infections. These policies include, but are not limited to, appropriate procedures for surveillance and reporting of infections, housekeeping, handling and disposal of waste and contaminants, and sterilization and disinfection, including the sterilization and maintenance of equipment. Where dialysis supplies are reused, there are written policies and procedures covering the rinsing, cleaning, disinfection, preparation, and storage of reused items which conform to requirements for reuse in §405.2150.	Interpretive Guidelines: §405.2140(b)(1) As a surveyor, practice standard precautions while conducting your survey. The written policies in a particular facility may state that they do not have the proper physical facility to provide adequate isolation of hepatitis-positive patients. This is acceptable as long as the facility has a written policy that states their position. If the facility chooses to treat hepatitis positive patients, however, the facility should follow the recommendations of the CDC which says that hepatitis-positive patients should be dialyzed separate from non-hepatitis patients (ideally in a separate room on a machine that is not used for non-hepatitis patients). The CDC also recommends that the staff assigned to hepatitis-positive patients not treat non-hepatitis positive patients at the same time. The CDC does not recommend special treatment for patients with the human immunodeficiency virus (HIV) or hepatitis C virus (HCV). Infection control procedures also include control of microbial contamination in water and dialysate (see §405.2140(a)(5)), and dialyzers and other devices which are reused (see §405.2150). In addition, the facility should have infection control strategies (e.g., disinfection and decontamination procedures) that are employed for particular medical devices used in the facility

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		Interpretive Guidelines: §405.2140(b)(1) (Cont.)-- The facility's infection control strategies should cover at least the following: o A written plan that is reviewed and updated as necessary to reflect significant changes in tasks and procedures; o A requirement for the use of personal protective equipment, such as gloves, gowns, or face protection, when necessary; o A requirement for housekeeping procedures that ensure that the environment is clean and sanitary; o A requirement for efficient and safe infectious waste disposal; o A requirement for effective handling of blood contaminated linens and clothing; o Development and implementation of an effective training program for the use of infection control practices; o A procedure for maintaining employee's medical records, including results of all medical examinations, vaccinations, and incidents of exposure; o Maintenance of employee's training records with respect to infection control training; o Disinfection policies and procedures for medical equipment and medical devices, including periodic bacteriological testing of a random sample of dialysis machines; o Procedures for maintaining a log of adverse patient reactions; and o Procedures for monthly surveillance of dialysate and water.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		Interpretive Guidelines: §405.2140(b)(1) (Cont.)-- The CDC can offer educational assistance to the dialysis facility that is unable to control hepatitis or other infections, or a facility that is experiencing problems with pyrogenic reactions or bacteriological contamination. You can inform the ESRD facilities of the availability of the CDC consultant resource for specific questions pertaining to pyrogenic reactions, bacterial contamination, disinfection procedures, or water treatment procedures. Notification of serious outbreaks of diseases must be reported to State Health Departments. It is the custom of the CDC to enter a facility only upon the request of the State Health Department. If a facility requests their consultation, the CDC will contact the State Health Department to ensure coordination. Survey Procedures and Probes: §405.2140(b)(1) Observe the staff as they care for the patients. They should practice standard precautions. They should change gloves between patients (observe staff with several patients), wash hands between patients, place uncapped needles in puncture-proof containers which are near enough to allow staff to dispose of the needle easily, wear gloves and protective clothing when tearing down/cleaning equipment, surface clean all dialysis equipment with disinfectant between each patient and remove protective clothing and gloves before leaving the dialysis unit. Ask the facility staff member(s) responsible for this activity the following questions: How do you assess the risk for infectious and communicable diseases? How do you identify patients at risk for infectious and communicable diseases? How are staff members educated about infectious and communicable diseases? How are staff screened for communicable diseases? How are staff evaluated when they are exposed to communicable diseases? What evidence is there that contaminated laundry is disposed of properly? How does the facility provide a safe environment which is consistent with the most recent CDC and OSHA recommendations for infection control and prevention?

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V267	(2) Treatment areas are designed and equipped to provide adequate and safe dialysis therapy, as well as privacy and comfort for patients. The space for treating each patient is sufficient to accommodate medically needed emergency equipment and staff and to ensure that such equipment and staff can reach the patient in an emergency.	Interpretive Guidelines: §405.2140(b)(2) Coordinate the survey of this requirement with §405.2138(c) concerning privacy requirements for the patient.
V268	There is sufficient space in units for safe storage of self-dialysis supplies.	§405.2140(b)(2)
V269	(3) There is a nursing/monitoring station from which adequate surveillance of patients receiving dialysis services can be made.	Interpretive Guidelines: §405.2140(b)(3) Nursing/monitoring stations do not have to be in the direct line of sight. Various means of monitoring can be used including audio, television, or other methods which will allow the staff to ensure adequate surveillance. Some units may have multiple nursing/monitoring stations.
V270	(4) Heating and ventilation systems are capable of maintaining adequate and comfortable temperatures.	Interpretive Guidelines: §405.2140(b)(4) Patients may need warm temperatures in the facility because of lowered body temperatures during the dialysis. These temperatures may be too warm for the staff. Survey Procedures and Probes: §405.2140(b)(4) How does the facility determine the temperature of the facility for "comfort?" Ask patients what response is made if they complain about facility temperatures.

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V271	(5) Each ESRD facility utilizing a central-batch delivery system provides, either on the premises or through affiliation agreement or arrangement (see §405.2160) sufficient individual delivery systems for the treatment of any patient requiring special dialysis solutions.	Interpretive Guidelines: §405.2140(b)(5) Facilities must provide the prescribed dialysate solution to each patient, even if the facility must order and use dialysate that is not normally used by a majority of patients in the unit. Survey Procedures and Probes: §405.2140(b)(5) In your survey, look for congruence of dialysate ordered and dialysate provided to the patient. How does the facility assure that patients get the proper dialysate solutions?
V272	(c) Standard: Contamination prevention. The facility employs appropriate techniques to prevent cross-contamination between the unit and the adjacent hospital or public areas including, but not limited to, food service areas, laundry, disposal of solid waste and blood-contaminated equipment, and disposal of contaminants into sewage systems.	Interpretive Guidelines: §405.2140(c) Laundry that is contaminated with blood should be handled as little as possible, bagged at the location where it is used, and not sorted or rinsed in patient areas. The contaminated laundry should be placed and transported in bags that are labeled or color coded. Employees of the facility who process laundry should wear protective gloves and other appropriate personal protective equipment to prevent occupational exposure. Note: Very few units do their own or have their own laundry. Most use disposable "linen" and patients bring their own blankets. Survey Procedures: §405.2140(c) Observe/ask what patients are to do when their clothing is soiled with blood. Observe actions/instructions of staff when patient clothing or blankets are soiled with blood.
V273	Waste storage and disposal are carried out in accordance with applicable local laws and accepted public health procedures	Interpretive Guidelines: §405.2140(c) The plan for the disposal of waste products should ensure that all waste destined for disposal is placed in appropriate leak-proof containers or bags that are properly color-coded or labeled as required and that sharps are disposed of in easily accessible closable containers which are puncture resistant and leak-proof and are labeled or color-coded accordingly. Containers should be securely closed and stored in non-patient areas.

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V274	The written patient care policies (see §405.2136(f)(1)) specify the functions that are carried out by facility personnel and by the self-dialysis patients with respect to contamination prevention.	§405.2140(c)
V275	Where dialysis supplies are reused, records are maintained that can be used to determine whether established procedures covering the rinsing, cleaning, disinfection, preparation and storage of reused items, conform to requirements for reuse in §405.2150.	Interpretive Guidelines: §405.2140(c) If the facility reuses and reprocesses dialysis supplies, they must develop procedures for contamination control specified in §405.2150.
V276	(d) Standard: Emergency preparedness. Written policies and procedures specifically define the handling of emergencies which may threaten the health or safety of patients. Such emergencies would exist during a fire or natural disaster or during functional failures in equipment. Specific emergency preparedness procedures exist for different kinds of emergencies.	§405.2140(d)
V277	These are reviewed and tested at least annually and revised as necessary by, or under the direction of, the chief executive officer.	§405.2140(d)

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V278	All personnel are knowledgeable and trained in their respective roles in emergency situations.	§405.2140(d)
V279	(1) There is an established written plan for dealing with fire and other emergencies which, when necessary, is developed in cooperation with fire and other expert personnel.	§405.2140(d)(1)
V280	(2) All personnel are trained, as part of their employment orientation, in all aspects of preparedness for any emergency or disaster. The emergency preparedness plan provides for orientation and regular training and periodic drills for all personnel in all procedures so that each person promptly and correctly carries out a specific role in case of an emergency.	Interpretive Guidelines: §405.2140(d)(2) This standard calls for periodic drills for all personnel in emergency procedures. These drills are intended primarily for the benefit of personnel, to rehearse the procedures and details worked out in the facility's plans to handle the emergency or disaster. However, because of the nature of the patients being artificially restrained by means of the dialysis mechanism, the movement of patients during drills to safe areas or to the exterior of the building is not required. Drills should be conducted periodically on each shift to familiarize the staff and patients with signals and emergency action required under varied conditions. The purpose is to test the efficiency, knowledge, and response of the staff and ensure patients that safe care will be provided in emergencies. It is not to disturb or excite patients. Patients, including self dialysis patients, should be instructed in the staff's plan to respond to emergencies, such as fires.

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V281	(3) There is available at all times on the premises a fully equipped emergency tray, including emergency drugs, medical supplies, and equipment,	Interpretive Guidelines: §405.2140(d)(3) The facility should have emergency equipment available at all times in the immediate vicinity of the patient treatment area. The equipment required is not specified. However, it should include drugs and supplies which would be needed in a medical emergency. Examples are oxygen and compressed air, mechanical ventilatory assistance equipment, cardiac defibrillator, monitoring equipment, laryngoscope, and suction equipment.
V282	and staff are trained in its use.	Interpretive Guidelines: §405.2140(d)(3) Staff must be trained in the use of emergency equipment. If the facility requires a defibrillator to be a part of the emergency equipment it should be tested periodically (there should be a record of the tests) and the batteries (if used in the defibrillator) should be fully charged. Survey Procedures and Probes: §405.2140(d)(3) Ask the staff how they have been trained in the use of the equipment and in the procedures needed in emergency situations. Look for evidence in personnel records for an indication that periodic training has been held and that staff has shown proficiency in the use of the equipment.
V283	(4) The staff is familiar with the use of all dialysis equipment and procedures to handle medical emergencies.	Survey Procedures and Probes: §405.2140(d)(4) Discuss with the staff the procedures they would follow in the event of a specific emergency. Ask what their role is in the event that a patient experiences a medical emergency, (e.g., stops breathing)?
V284	(5) Patients are trained to handle medical and nonmedical emergencies. Patients must be fully informed regarding what to do, where to go, and whom to contact if a medical or nonmedical emergency occurs.	Interpretive Guidelines: §405.2140(d)(5) It is the facility's responsibility to inform patients about what to do and where to go if they have an emergency outside the facility. The facility should also inform patients about how emergencies within the facility will be handled.

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		Survey Procedures and Probes: §405.2140(d)(5) Ask patients if they know what they are to do in the event of a fire or other emergency in the facility. Determine if they know who to call and where to go in the event of a medical emergency outside of the facility. What instructions do they have with respect to getting treatment if the weather is bad, e.g., heavy snow, flooding?
V300	§405.2150 Condition: Reuse of hemodialyzers and other dialysis supplies. An ESRD facility that reuses hemodialyzers and other dialysis supplies meets the requirements of this section. Failure to meet any of paragraphs (a) through (c) of this section constitutes grounds for denial of payment for the dialysis treatment affected and termination from participation in the Medicare program.	Interpretive Guidelines: §405.2150 This Condition discusses requirements for the reuse of hemodialyzers and other supplies, the use of chemical germicides, the surveillance of possible patient reactions resulting from reuse, and the proper handling of dialyzer end caps, transducer filters, and bloodlines. Survey for reuse primarily by observing the entire reprocessing sequence and interviewing the reuse technician. Confirmation or clarification by review of the policies are supplemental survey activities to be used only as indicated.
V301	(a) Standard: Hemodialyzers. If the ESRD facility reuses hemodialyzers, it conforms to the following: (1) Reuse guidelines. Voluntary guidelines adopted by the AAMI ("Reuse of Hemodialyzers," second edition). Incorporation by reference of the AAMI's "Reuse of Hemodialyzers," second edition, 1993, was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. If any changes in "Reuse of Hemodialyzers," second edition, are also to be incorporated by reference, a notice to that effect will be published in the FEDERAL REGISTER.	Interpretive Guidelines: §405.2150(a)(1) Standards of the Association for the Advancement of Medical Instrumentation (AAMI), 1993, for reuse of hemodialyzers is incorporated by reference 42 CFR 405.2150(a)(1) and are reflected in tags V302-V385. AAMI is a professional organization in which boards composed of representatives of the industry, providers, and regulatory agencies develop voluntary guidelines for medical products and procedures. AAMI's "American National Standard for Reuse of Hemodialyzers," 1993, was incorporated by reference and has the authority of regulation. Additional explanatory information from the AAMI rationale is included here for ease of reference. This standard should be cited if the facility's reuse practices do not comply with the AAMI guidelines.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
V302	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (4) Records. All records described in this recommended practice should meet the requirements for medical records, including completeness, legibility, and security. Place should be provided for the signature or other unique mark of identification of the person completing each step of the reprocessing procedure; i.e., the person performing preventive maintenance procedures, the person(s) investigating complaints, and the person(s) conducting quality assurance (QA) and quality control (QC) activities.	**AAMI Rationale for the Development and Provision of this Recommended Practice** (4) Records - Documentation is essential to a safe, effective hemodialyzer reprocessing program. The overall dialyzer reuse procedure documentation includes reference materials, procedures, and policies, some of which may be distributed in the facility for operating purposes. The other records serve to document aspects of the reuse procedure for each dialyzer, along with quality control (QC) and quality assurance (QA) measures, so that complete history of the reprocessing of each dialyzer and QC/QA procedures exists. The committee felt that when the useful life of a dialyzer is over, and no notable events have occurred, those reprocessing records need not be kept. Allowance is made for keeping the reprocessing record data in the reprocessing log, the patient's chart, or a combination of the two, since both of these are traceable, permanent records and it may be inconvenient to record all the information in one location. The committee decided not to include a specific recommendation for a checklist for initiating dialysis, because although this is a convenient way to ensure that the procedure is followed, the same purpose can be served by completing the recommended documentation for preparing the reprocessed dialyzer for dialysis (see 12.1, 12.2, and 12.4.1). Survey Probes: §405.2150(a)(1) Are reprocessing records complete, legible and secure? Are records signed or initialed by the appropriate reprocessing personnel? Are there records for maintenance of the reprocessing equipment, of results of complaint investigations, and of quality assurance activities?
V303	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (4.1) Dialyzer reprocessing manual The dialyzer reprocessing manual should be a compilation of all specifications, policies, training materials, manuals, methodologies, and procedures which may be integrated into the dialysis facility's policy and procedures manual. The dialyzer reprocessing manual should also contain samples of forms and labels, if appropriate. The operational logs, manuals, and files may be kept separate from the dialyzer reprocessing manual.	Survey Probes: §405.2150(a)(1) Does the dialyzer reprocessing manual include the following information: 1) All documents required by the AAMI recommended practice for the reuse of hemodialyzers, including procedures for: o rinsing and cleaning; o disinfection; o testing; o storage; and o setup for reuse?

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		Survey Probes: §405.2150(a)(1) (Cont.)-- 2) Procedures for maintenance and calibration of reprocessing equipment (both manual and automatic); 3) Test procedures and scheduling of tests for water quality; 4) Procedures for facility inspections of environmental conditions; 5) Operating manuals for automated reprocessing equipment, including deviations from the manufacturer's instructions which may have been instituted by the facility; 6) Acceptance criteria for cleaning solutions and disinfectants used with the reprocessing equipment; 7) Complete process protocols developed by the facility for manual reprocessing equipment; and 8) Records required by other sections of the AAMI guidelines?
V304	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (4.2) Reprocessing record Records must be kept that identify the new dialyzer, the date of each reprocessing step, the person performing the procedure, their signature or other identifying mark, and the results of tests of device performance and safety. This information should be recorded in a reprocessing log or the patient's chart, whichever is more convenient. Patients should be permitted to read records pertaining to the reprocessing and reuse of their own dialyzers.	Survey Procedures and Probes: §405.2150(a)(1) Does the facility maintain records that can determine how each dialyzer was reprocessed, who performed the procedure, and when it was reprocessed? Portions of the reprocessing record may be documented on patient treatment records; other portions may be documented on reprocessing forms. Does the patient have access to these records?

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V305	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (4.3) Equipment maintenance record A log must be maintained of the date of preventive maintenance procedures and the date of results of scheduled testing in order to ensure the proper functioning of reprocessing equipment, environmental-control equipment, safety equipment, or other equipment.	Survey Probes: §405.2150(a)(1) Are logs being maintained which show dates of preventive maintenance and calibration of the reprocessing equipment? Do these dates correspond with the facility's set schedule?
V306	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (4.4) Personnel health monitoring records A file must be kept of the results of medical examinations of personnel to monitor exposure to substances of known or suspected toxicity that may be required by OSHA or other regulatory agencies.	Survey Probes: §405.2150(a)(1) Are personnel exposed to potentially toxic substances monitored? Do personnel files reflect the results of periodic medical examinations performed on reprocessing technicians?
V307	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (4.5) Complaint investigation record A file must be kept of all complaints by patients and staff about failures of reprocessed dialyzers or possible adverse reactions to reprocessed dialyzers; the results of a comprehensive investigation of these alleged problems; and if appropriate, the corrective actions taken. The file should be reviewed periodically for trends that may contribute to patient morbidity and mortality.	Survey Probes: §405.2150(a)(1) Are complaint files maintained? Are complaints investigated and results recorded? Is there an indication that complaint files are monitored for trends that might contribute to patient morbidity and mortality? Is there an indication how the complaint was resolved?

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V308	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (4.6) Quality assurance and quality control record A record must be kept of the date and results of QA and QC evaluations and the person(s) conducting the evaluations.	Interpretive Guidelines: §405.2150(a)(1) Records should include direct observation of reprocessing by an objective individual, i.e., someone not directly involved in the process such as the director of nursing or administrator.
V309	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (5) Personnel qualifications and training (5.1) Qualifications Personnel should possess adequate education or experience to understand and perform procedures outlined by the individual dialysis facility relevant to the facility's multiple use program. These people currently range from those with no medical background who are fully trained by the facility, to licensed practitioners with extensive medical background.	**AAMI Rationale for the Development and Provision of this Recommended Practice** (5) Personnel qualifications and training - The committee did not accept a proposal to include curriculum covering the entire range of technical activities related to dialysis. It was felt that more limited training is appropriate as a minimum for personnel who are not involved in other aspects of dialysis. A proposal to recommend that training could be less extensive for personnel with relevant previous training also was not accepted since certification of training (see 5.2.2) renders the recommendation superfluous. Survey Procedures and Probes: §405.2150(a)(1) Do personnel involved in reprocessing have adequate education and/or experience to perform the assigned tasks? Make your evaluation based on interview of the person(s) responsible for daily reprocessing of dialyzers. Are they familiar with these requirements and with the operation/maintenance of the equipment in use?

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V310	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (5.2) Training (5.2.1) Curriculum The dialysis facility's physician/director shall establish a training course for the persons performing hemodialyzer reprocessing. A written document should give details about the curriculum and should in particular address the potential risks to patients and staff of not following correct procedures. The curriculum should include at least the following information: a) the facility's specific reprocessing procedure, including a rationale for each step; b) basic documentation requirements of the program; c) the operation and maintenance of the facility's specific equipment for reprocessing hemodialyzers and, if appropriate, the dialysis systems and components; d) microbiology with respect to aseptic technique, the collection and handling of samples, and personnel safety; precautions for infectious hazards; e) the risks and hazards of multiple use of hemodialyzers; f) the consequences of not performing tasks properly;	Survey Procedures and Probes: §405.2150(a)(1) Does the facility maintain records which outline the curriculum for various courses required of the reprocessing personnel? Does the curriculum contain at a minimum the information listed here? Interview the reuse technician(s) to verify their knowledge of curriculum content. If you identify problems, review the curriculum and the personnel file of the individual(s) interviewed. Observe the entire reprocessing sequence. If you identify potential deficiencies, review the specific procedure for the step in which the deficiency is identified.

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	g) the risks and hazards associated with toxic substances used in reprocessing hemodialyzers, proper handling of these substances, and procedures for handling spills and proper disposal of toxic substances; h) the use and location of protective eyewear, respirators, masks, and special clothing; i) emergency procedures as required by the facility; j) the principles of dialysis, emphasizing the characteristics of the hemodialyzer.	
V311	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (5.2.2.) Documentation Each person performing procedures for the multiple use of dialyzers must have successfully completed the dialysis facility's training course relevant to their task and demonstrated competence in the area covered by their training. Successful completion of training should be certified by the medical director or his or her designated representative and recorded in the person's personnel file along with the trainee's verification of having received the instruction. Retraining is necessary when new procedures are undertaken	Survey Procedures and Probes: §405.2150(a)(1) Has the physician/director certified that reprocessing personnel have successfully completed the required courses? Written examinations should be scored.

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V312	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (6) Patient considerations (6.1) Medical issues A decision to reprocess hemodialyzers should be made by a physician knowledgeable about reprocessing and its medical and economic implications. Dialyzers shall not be reprocessed from patients who have tested positive with hepatitis B surface antigens. Precautions for all infectious hazards should be emphasized and included in the reprocessing procedures. Written procedures shall stipulate whether and how reprocessing will be done for patients who have shown sensitivity to materials used in the reprocessing of hemodialyzers. Since the current human immunodeficiency virus (HIV) or hepatitis B status of the patient cannot be known with certainty, all staff potentially exposed to patients' blood should observe universal precautions.	**AAMI Rationale for the Development and Provision of this Recommended Practice** (6.1) Medical Issues - The primary objective of the committee was not to recommend medical indications for reprocessing or to evaluate the medical or economic implications of reprocessing, but to provide recommendations for safe reuse practice. Many professionals consider the "first-use syndrome," to be a specific indication for reprocessing. At the time of this writing, the Centers for Disease Control (CDC) does not object to reprocessing and reusing dialyzers from patients with hepatitis C due to lower viral burden. CDC is also not opposed to the reprocessing of dialyzers from patients with known HIV infection. The committee recommends, however, that universal precautions be used in the reprocessing of all dialyzers. These precautions include the use of gowns, masks, and gloves. Each facility must be aware of the hazards of infection and set policies accordingly. Survey Procedures and Probes: §405.2150(a)(1) Is there a written policy explaining the facility's position with respect to reuse? Does the policy explain that the facility will not reprocess dialyzers from patients who have tested positive for hepatitis B? Dialyzers of patients of unknown hepatitis B status should not be reused. Do personnel handling dialyzers and performing reprocessing observe standard precautions? Impervious aprons including sleeve covers, gloves and face shields should be worn during procedures when there is potential for splashing, spray of fluids, or germicide. Be sure to don protective gear during your observation of reprocessing.

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V313	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (6.2) Informed consent Opinions differ about the need for specific informed consent for reprocessing hemodialyzers. If informed consent specifically for hemodialyzer reprocessing is obtained, the informed consent form should be in the medical record. The physician director and staff are responsible for fully informing patients of the dialysis facility's practices with regard to reuse of hemodialyzers and other dialysis supplies.	**AAMI Rationale for the Development and Provision of this Recommended Practice** (6.2) Informed consent - The committee decided, upon legal advice, that it is not appropriate for an AAMI recommended practice to suggest elements of informed consent, although this section originally contained them. The committee considered the following arguments about this issue. Those who believe that specific informed consent for the use of reprocessed hemodialyzers is required maintain that greater patient participation in the therapeutic process need not impair the physician's ability to deliver quality care. Rather, they say, involvement ensures that quality care will remain the primary impetus of decision to reuse. It is also asserted that for most patients honest, trusting interaction with their personal physicians is a sufficient guarantee of quality, but the imposition of a dictatorial relationship may lead patients to seek recourse through legal means. Those who do not agree with informed consent specifically for multiple use of hemodialyzers point out that specific consent could be counter productive due to the confusion that could be created by personal preferences for, as examples, length of dialysis, choice of blood flow, fluid removal rate, etc. They argue that multiple use of hemodialyzers can properly be implied in the consent for hemodialysis therapy just as are other treatments. The topic of physician/patient relationships is important to mention in view of the concerns of some patients about the adequacy and safety of reprocessing procedures and the possibility that financial savings from the multiple use of hemodialyzers might contribute to the economic benefit of others rather than to improve the quality of care. The committee also considered the question of the right to freedom of choice not to participate in a hemodialyzer reprocessing program. Consensus could not be reached on this issue because of the underlying conflict between individual self-determination and financial constraints imposed by society (see Rettig, 1982).

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		AAMI Rationale for the Development and Provision of this Recommended Practice (6.2) Informed consent - continued Fear of increased risk, anger over presumed profits, and frustration surrounding consent issues have been expressed by some patients. Establishing QA practices such as those recommended here and sharing information with patients to educate them, responding to questions and eliminating any impression of secrecy are encouraged as effective solutions to these problems. The fact that the majority of dialysis facilities reprocess hemodialyzers and the long history of this technique support the conclusion that the multiple use of hemodialyzers is customary medical practice. Courts might find that consent for dialyzer reprocessing per se is not required, but this issue has not yet been adjudicated. Survey Procedures and Probes: §405.2150(a)(1) Does the facility have a written policy defining its position with respect to informed consent specifically for dialyzer reuse? Is the consent form in the medical record? Consent for dialyzer reuse may be combined with the consent for hemodialysis treatment.

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V314	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (7) Equipment Each piece of equipment used for reprocessing must be appropriately designed, constructed, and tested to perform its intended task. Types of reprocessing systems vary from sophisticated microprocessor-controlled systems to hand operated valving systems. Satisfactory operation of manual and automated systems should be ensured by appropriate functional tests. Strict quality control (QC) must be maintained for either type of dialyzer reprocessing equipment. Additionally, complete documentation of system function, operation procedures, potential system failures and dialyzer-reuse criteria must be in the dialyzer reprocessing manual, known to the operator and available for review.	**AAMI Rationale for the Development and Provision of this Recommended Practice** (7) Equipment - Validation of dialyzer performance and the concentration of germicide was initially recommended after the repair of automated equipment to guard against possible faulty functioning of this complex apparatus. The recommendation was tempered by the words " if appropriate" for manual systems because the replacement of hoses, valves, and the like in these simple systems will not affect performance. The recommendation was subsequently changed to testing the function of the reprocessing system because the committee judged that demonstration of proper system function is an adequate QC measure. An earlier recommendation that the system prevent cross-contamination of water used for reprocessing and water used for dialysis was based on an episode in which water containing formaldehyde was introduced into water used for dialysis. The committee decided to delete this recommendation because the mishap was not attributable to a reprocessing system (the formaldehyde was put into the water system for dialysis to disinfect it) and because it may be desirable to use the same source for the water used for dialysis as the water used for reprocessing hemodialyzers in order to achieve the recommended water quality. It is particularly important that all water that comes into contact with the fluid pathways for blood or dialysate be of recommended quality because the blood side of the dialyzer might take up endotoxin that could be released into the circulation during the subsequent dialysis. Survey Procedures and Probes: §405.2150(a)(1) Does the facility have records to validate that the equipment will operate as required? Ask the reuse technician-- o how he/she validates the volume measurement done by automated equipment? o who maintains the equipment? o how he/she was trained to do this maintenance?

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V315	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (7.1) Water systems The system providing water for reprocessing must meet all the requirements for pressure, flow rate, bacteriological and pyrogenic contamination, and other requirements for operating the reprocessing equipment under minimal and peak load conditions.	Survey Probes: §405.2150(a)(1) Has the physician/director pointed out that appropriate water treatment be used to assure that the water used in the reprocessing area can routinely meet the maximum allowable chemical, bacteriological, and pyrogenic contaminates specified? Does the facility have written protocols for proper maintenance, calibration, and testing to assure that the water system can meet the necessary requirements? Does the facility maintain operational logs indicating that the system is being maintained and operated as specified?
V316	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (7.1.1) Disinfection The design of the water system should facilitate easy cleaning and disinfection of the entire system. Disinfection of the water system, including any booster pumps and water storage tanks, should be done whenever necessary to achieve the quality of water specified in 11.2.2 and 11.4.1.2. The disinfection procedure must include purging all portions of the system so that the residual germicide is reduced to safe levels as demonstrated by an appropriate test. The dates of disinfection and the dates and results of tests for residual disinfectant should be recorded in the equipment maintenance record (see 4.3), accompanied by the signature or other unique means of identification of the person performing the procedure.	Survey Procedures and Probes: §405.2150(a)(1) Is the water treatment system disinfected as needed? Are dates of disinfection and dates of results of tests for disinfection recorded? Ask the reuse technician: o How often he/she disinfects the water system? o How he/she decides to disinfect the water system? o What and where he/she tests to ensure the disinfectant is rinsed clean from the system?

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V317	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (7.1.2) Testing water quality Product water used for rinsing, cleaning, and to dilute the germicide must be tested for the degree of bacterial and/or endotoxin contamination as specified in 11.2.2 and 11.4.1.4. Water bacteriology monitoring should be carried out where the dialyzer is connected to the reuse system or as close as possible to that point.	Survey Procedures and Probes: §405.2150(a)(1) Is water used to prepare germicide tested to assure that the bacterial levels are no greater than specified at V343, i.e., bacterial count of <200 CFU/ml or LAL of 5 E.U. ? Is monitoring for water bacteriology being done where the dialyzer is connected to the reuse system or as close as possible to that point? Ask the reuse technician: o What the test limits are for water cultures? o Does he/she do LAL testing? o Where does he/she draw the sample for testing?
V318	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (7.2) Reprocessing systems (7.2.1) Utility requirements The quality, pressure, flow rate, and temperature of the water used for reprocessing should be specified in the dialyzer reprocessing manual, established before the initiation of a reprocessing program, and maintained thereafter. The manufacturer's or designer's recommendations for the water supply should be followed. Provision should also be made for adequate drains, ventilation, and electrical power.	Survey Procedures and Probes: §405.2150(a)(1) Ask the technician if there are limits for pressure, flow rate, and temperature of the water used for reprocessing. If he/she doesn't know, check the dialyzer reprocessing manual for specific requirements and cite at V309. Observe the reuse area for adequate drain, ventilation, and electrical power.

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V319	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (7.2.2) Process control testing Dialyzer test methods (11.3) and the test for the concentration of germicide shall be established prior to clinical use of the reprocessed dialyzers (see 11.4.1.5 and 12.3.2 or 12.3.3). For automated systems, this can be done by following the manufacturer's instructions. For manual systems, this can be done by confirming the accuracy of total cell volume (TCV) measurement and germicide concentration. Verification of tests should be repeated after each significant change in the reprocessing system.	Survey Procedures and Probes: §405.2150(a)(1) Has the facility verified the methods it uses to test a reprocessed dialyzer? If the facility has made a significant change in its reprocessing system, do records reflect that verification has been performed prior to clinical use of the reprocessed dialyzers?
V320	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (7.2.3) Maintenance Written maintenance procedures and a schedule of preventive maintenance activities designed to minimize equipment malfunctions should be established. In the case of purchased reprocessing equipment or safety equipment, the recommendations of the vendor should be followed unless alternative approaches are supported by documented experience. If these guidelines are not available, inspection should be semiannual. A record should be kept of preventive maintenance activities (see 4.3), accompanied by the signature of the person performing the maintenance.	Survey Procedures: §405.2150(a)(1) Ask the reuse technician if the facility has a schedule of preventive maintenance for reprocessing equipment. Ask the reuse technician to show you the log of when these maintenance activities were performed.

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V321	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (7.2.4) Repairs If the reprocessing system fails to function as expected, the problem should be investigated and repaired by qualified personnel. The reprocessing system function testing should be repeated after repairs of automated equipment and, if appropriate, after repairs of manual equipment before the reprocessed hemodialyzer is used for clinical dialysis.	Survey Procedures and Probes: §405.2150(a)(1) Do operational logs indicate when repairs were performed and who performed them? Ask the reuse technician to tell you: o What happens when the reprocessing system breaks down? o How he/she assures that repairs were successful?
V322	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (8) Physical plant and environmental safety considerations (8.1) Reprocessing area and ventilation The reprocessing area should be designed to suit the operation carried out and to maintain acceptable ambient concentrations of harmful substances. The area should be kept clean and sanitary. It may be part of the dialysis treatment area, as long as properly designed and vented equipment is used that meets the requirements for environmental safety (see 8.5).	**AAMI Rationale for the Development and Provisions of this Recommended Practice** (8) Physical plant and environmental safety considerations - A proposal that the reprocessing area be supplied with HEPA-filtered air, a laminar flow station and positive pressure to surrounding areas was not accepted, because these measures to control bacterial contamination were deemed inappropriate for reprocessing since the exposure of the dialyzer to bacterial contamination is limited to making connections comparable to setting the device up for dialysis. Another proposal that the reprocessing area be negatively pressurized to control odors was not accepted because the committee agreed that odor control can be achieved by other methods. The committee also determined that it was not necessary to recommend facility design, since a number of configurations have been shown to be satisfactory, including the use of automated equipment in the dialysis treatment area. The statement about personnel health monitoring was included in response to a comment referring to the CFR (Chapter 29, Part 1910.20) which addresses access to employee exposure and medical records. The committee is unaware of any state department of public health that requires personnel health monitoring in this area, but the states themselves are another possible source of information on this question. Survey Procedures: §405.2150(a)(1) Notice if you are bothered by smells or fumes of germicide. If so, ask the reuse technician to perform air-level testing. Observe the reuse area. Reprocessing is the “re-manufacturing” of a medical device which has direct contact with patients’ blood. The area should be clean and sanitary at all times.

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V323	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (8.2) Storage area Reprocessing materials, devices awaiting reprocessing, and reprocessed devices should be stored so as to minimize deterioration, contamination, or breakage. Segregation of new, used, and reprocessed dialyzers should be maintained to make clear the status of each group of dialyzers. When appropriate, environmental contamination of the storage area should be controlled and monitored. Storage areas for new dialyzers and reprocessing materials should be designed to facilitate rotation of stock and cleaning. Storage arrangements should also take into account fire safety considerations, OSHA, and other appropriate regulations.	Survey Procedures: §405.2150(a)(1) Observe the storage of dialyzers. "Clean" and "dirty" should be stored separately in a manner which prevents contamination of the "clean" dialyzers.
V324	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (8.3) Laboratory area Tests that do not require special facilities, such as certain tests for germicide levels, may be done in the reprocessing or dialysis treatment area, whichever is appropriate.	Survey Procedures: §405.2150(a)(1) Observe where tests are performed. These may include tests for germicide presence, absence and concentration as well as water cultures and LAL testing.

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V325	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (8.4) Personnel protection Durable gloves and protective clothing should be worn when handling the dialyzer during initiation and termination of dialysis and during the reprocessing procedure. Universal precautions shall be observed. Eye protection should be worn when performing steps that may result in spills or splashes of substances of known or suspected toxicity. These agents should only be handled in areas with adequate ventilation, washing facilities, eye wash stations, appropriate respirators, and spill control materials. When handling concentrated toxic substances, aprons impervious to these substances should be worn.	Survey Procedures and Probes: §405.2150(a)(1) Does the facility supply appropriate safety equipment? Does the facility's policy state that appropriate safety equipment must be worn during reprocessing? Is training in the use of this equipment provided? Are personnel using the specified safety equipment? Where are eye wash stations, showers, spill control materials, and respirators located? Note that different germicides may, per OSHA, require different spill control equipment. For example, facilities using formaldehyde must have a quick drench shower available while facilities using germicides are not required to have showers.

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V326	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (8.5) Environmental safety The dialysis facility should have written procedures for safe storage and handling of chemicals used in reprocessing (see National Institute of Safety and Health (NIOSH)/OSHA, 1980 and Sax, 1979 cited in annex D, and material data safety sheets cited in section 3 for useful information). Vapors from reprocessing materials should be maintained below potentially toxic levels (see table 1).	Interpretive Guidelines: §405.2150(a)(1) **Table 1 - OSHA Environmental exposure limits (29 CFR 1920-1990)** Substance/Material — Limits Formaldehyde — 0.75 ppm TWA 3 ppm STEL 0.5 ppm action level Glutaraldehyde — 0.2 ppm Phenol — 5 ppm TWA Acetic acid — 10 ppm Paracetic acid — None developed Chlorine dioxide syn: Chlorine oxide — 0.1 ppm TWA Hydrogen peroxide — 1 ppm TWA TWA = timed weighted average STEL = short term exposure limit ppm = parts per million Survey Procedures and Probes: §405.2150(a)(1) Observe the handling and storage of germicides for safety. Are toxic vapors from germicides being monitored as necessary? Do you notice smells or fumes in the reuse or treatment area?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
V327	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (9) Reprocessing supplies (9.1) Specifications and testing Each reprocessing material should meet a certain level of quality that ensures its suitability for the intended purpose. This requirement may be determined by certification by the supplier of the product that the product meets necessary specifications, or by relevant identification or testing procedures by trained personnel, as appropriate. When testing is performed, a log of the date, the identifying number for the delivery or batch, and test results should be maintained.	**AAMI Rationale for the Development and Provisions of this Recommended Practice** (9.1) Specifications and testing - Testing of all incoming materials had been proposed. In recognition of the fact that most medical supplies are certified by the vendor and not tested by the user, the committee decided to recommend that supplies need not be tested by the facility doing hemodialyzer reprocessing if they are marketed for hemodialyzer reprocessing. The importance of trained personnel evaluating the supplies is illustrated by an instance where formaldehyde contained a hydrocarbon contaminant from a storage tank. This is also the rationale for recommending USP grade formaldehyde. Survey Procedures and Probes: §405.2150(a)(1) Are specifications for materials used in the reprocessing program in the dialyzer reprocessing manual? Is incoming material checked for its potency? Are results of tests maintained in appropriate files? Ask the reuse technician how he/she ensures that the supplies used (germicide, dialyzers, lines) are of acceptable quality.
V328	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (9.2) Inventory Control Reprocessing supplies should be used on a first-in, first-out basis, and outdated supplies should be identified and discarded.	**AAMI Rationale for the Development and Provisions of this Recommended Practice** (9.2) Inventory control - The committee suggests that supplies should be used on a first-in, first-out basis to avoid deterioration over time in storage. Survey Procedures: §405.2150(a)(1) Ask the reuse technician how he/she rotates stock.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
V329	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (10) Hemodialyzer labeling Each reprocessed hemodialyzer must be used for only one patient. The labeling therefore must uniquely identify the patient who is using the dialyzer. The dialyzer should also be labeled with other information essential to proper reuse procedure.	Interpretive Guidelines: §405.2150(a)(1) Reprocessed hemodialyzers must be used for the same patient. The labeling therefore must uniquely identify the patient who is using the dialyzer. The dialyzer should also be labeled with other information essential to proper reuse procedure. Survey Procedures: §405.2150(a)(1) Inspect reprocessed dialyzers for unique identification of an individual patient.
V330	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (10.1) Time of labeling Each hemodialyzer should be labeled prior to or at the first use of the device, and the label should be updated after each use (see 10.3).	**AAMI Rationale for the Development and Provisions of this Recommended Practice** (10.1) Time of labeling - The dialyzer to be reprocessed should be labeled prior to or at the first use to ensure that the patient will be correctly identified and to have the label available for the information recommended in 10.3. Survey Procedures: §405.2150(a)(1) During your observation of the treatment area, verify that all dialyzers to be reused are labeled with the patient's name. Used dialyzers brought to the reuse room which are not labeled with the patient's name must be discarded.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
V331	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (10.2) Label composition Markings should be resistant to normal reprocessing and dialysis procedures. The dialyzer labeling should not obscure the manufacturer's model number, lot number, or indicators of the direction of blood and/or dialysate flow or other pertinent information, unless provision is made for recording this information on the label. The label on hemodialyzers with transparent casings should permit the blood path to be readily inspected.	**AAMI Rationale for the Development and Provisions of this Recommended Practice** (10.2) Label composition - The committee recommended using indelible ink to label the dialyzer, but changed the recommendation to any method resistant to normal reprocessing and use procedures; other satisfactory materials exist, and requiring indelible ink might preclude some techniques, such as bar coding. Survey Procedures and Probes: §405.2150(a)(1) Inspect reprocessed dialyzers: o Is the label intact? o Can you see the manufacturer's model and lot number? o Is there a clear area where you can follow the blood path from one end of the dialyzer to the other without obstruction?
V332	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (10.3) Information recorded The dialyzer must be labeled with the patient's name, the number of previous uses, and date of the last reprocessing. Dialyzers of patients with similar last names should have a warning to the user to take extra care in ensuring that the name or other identifying information on the label corresponds to that of the patient. If there is sufficient room, the dialyzer may also be labeled with the results of tests, the signature or other unique means of identification of the person performing the various steps in the reprocessing procedure, and the reference values for performance parameters. When this information appears on the label, a permanent record should also be kept (see 4.2).	**AAMI Rationale for the Development and Provisions of this Recommended Practice** (10.3) Information recorded - A proposal that the label contain all of the recommended information was not accepted because space limitations may make this impractical, and there is no need to have all of the information on the label. Display of the number of previous uses on the label is recommended so that this information is readily available. The date of the last reprocessing facilitates verification that sufficient time has elapsed since the introduction of the germicide to achieve sterilization or disinfection. Home dialysis patients are exempted from the recommendation that the patient's name appear on the label where confusion with another patient's dialyzer will not occur. Survey Procedures: §405.2150(a)(1) Inspect reprocessed dialyzers for these elements. Ask the reuse technician and the dialysis treatment staff what method is used to alert staff of patients with the same or similar names. Remember that dialyzers and their labels are eventually discarded; a permanent record is needed of information recorded on the label.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
V333	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (11) Reprocessing The multiple use of a dialyzer begins with the labeling of the new dialyzer (see section 10) and then continues with the reprocessing procedures described in this section. Preparation of the reprocessed dialyzer for the next dialysis is described in section 12. The cycle is repeated after the next use of the dialyzer until the dialyzer does not meet the criteria for continued use. A systems diagram of these procedures is given in annex C (normative). The results of the tests and the signature or other unique means of identification of the person performing each step should be maintained in a permanent record (see 4.2). Completion of all reprocessing steps, tests and inspections should be documented in the reprocessing record, accompanied by the signature or other unique means of identification of the person completing them.	Survey Procedures: §405.2150(a)(1) Observe the entire reprocessing sequence. The order of your observations will vary dependent on schedules -- both yours and the facility's. Inform the facility representative(s) at the entrance conference that you will need to see all the steps of the process during your survey, and enlist their assistance in accomplishing this.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
V334	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (11.1) Transportation and handling Dialyzers should be handled and transported in a clean and sanitary manner. Persons handling used dialyzers during transportation should do so in a clean and sanitary manner maintaining universal precautions until disinfection is complete.	**AAMI Rationale for the Development and Provision of this Recommended Practice** (11.1) Termination of dialysis - It was recommended at first that only disinfected caps be used to occlude the ports of the dialyzer. This was modified to include caps from the same dialyzer maintained in a clean condition, based on experience indicating that this method is acceptable. It was decided later that this recommendation is adequately addressed by the general statement about handling the hemodialyzer in a clean and sanitary manner. Survey Procedures and Probes: §405.2150(a)(1) Observe the manner in which dialyzers are transported. Are basins clean? Where are open mesh baskets placed? Are floors/counters protected from spillage/leakage from used dialyzers? Personnel should use gloves to handle used dialyzers until disinfection is complete.
V335	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (11.2) Rinsing/cleaning (11.2.1) - Dialyzer reprocessing should be initiated in sufficient time to produce a reprocessed device that meets the requirements of 11.3. Each dialysis facility should establish its time limits. Staff involved in the handling, transport, or storage of dialyzers, locally or at remote locations, should take necessary precautions to prevent exposure to possibly infected blood.	**AAMI Rationale for the Development and Provision of this Recommended Practice** (11.2.1) Rinsing/cleaning - The committee considered stipulating a period of time after dialysis within which reprocessing must begin. Consensus was not reached on the period of time, and the committee decided that meeting performance guidelines is the goal of such a specification. Aqueous liquids rather than gases such as air are the preferred fluids for rinsing and cleaning (Bass et al., 1973). Some clinics have refrigerated dialyzers until they are reprocessed to retard bacterial growth and clotting. Survey Procedures and Probes: §405.2150(a)(1) Has the facility established criteria for the initiation of reprocessing? Generally, facility policies require refrigeration of dialyzers should it take longer than 2 hours to begin reprocessing. Observe the time taken to begin reprocessing after dialysis is completed. Are these criteria being followed? If reprocessing is performed offsite of the treatment center, ask how the facility ensures safe transport of the dialyzers. Transport temperature must be controlled for dialyzers being sent to the reprocessing site. Reprocessed dialyzers must be inspected on return to ensure the caps are intact and germicide has not leaked out. Precautions should also be taken to protect the transport vehicle/mechanism from contamination with blood or germicides. If reprocessing is done offsite, you will need to visit that location to observe the reprocessing steps done there.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
V336	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (11.2.2) - The dialyzer should be rinsed and cleaned with a fluid or fluids that enable it to meet the specification of 11.3. Both the blood and dialysate compartments should be flushed with a rinsing/cleaning solution. The water should have a bacterial colony count of less than 200 per ml or a bacterial lipopolysaccharide (LPS) concentration of less than 1 ng/ml as measured by the Limulus amebocyte lysate assay.	**AAMI Rationale for the Development and Provision of this Recommended Practice** (11.2.2) - A proposal that only treated water or physiological saline be used was not accepted at first, because some safe and effective techniques employ untreated water or nonphysiological concentrations of solute in the rinsing solution. The committee thought that the important goals were meeting the recommendations for satisfactory performance (see 11.3) and presence of a physiological solution in the dialyzer before starting dialysis (see 12.4). After further comment and review, the committee endorsed as a reasonable safeguard the use of water meeting AAMI bacteriological standards (AAMI, 1982) or having a maximum level of bacterial lipopolysaccharide (LPS) of 1 ng/ml. The chemical quality of the water is not specified because of lack of consensus on this issue. Although the committee agreed that high-quality water is not necessary to protect the patient from chemical contamination, it recognized that data exist suggesting that reprocessing with reverse osmosis quality water yields more reuses (F. Gotch, personal communication). The committee had included a recommendation that any device which interfaces between the blood compartment and the permanent equipment must be cleaned and disinfected between each hemodialyzer reprocessed. The recommendation was deleted because permanent equipment sometimes makes a direct connection with the hemodialyzer and because data demonstrating the need for the recommendation are lacking. Survey Procedures and Probes: §405.2150(a)(1) The dialyzer should never be exposed to tap water. The blood side of the membrane is exposed to water during reprocessing; patient injury could result from the use of unsafe water during reprocessing. Has the water used for rinsing been treated to assure that its bacterial and pyrogen content does not exceed these values? Facilities may do cultures or LAL testing. Ask how the bacterial levels in the water are monitored. Review test results to assure these limits are met. Observe the rinsing process. Rinsing should continue until the effluent is clear; a pink or brownish tinge to the effluent should result in continued rinsing.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
V337	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (11.2.3) Diluted solutions of hydrogen peroxide, sodium hypochlorite, peracetic acid, or other chemicals may be used as cleaning agents for the blood compartment, providing that the cleaning agent has been shown to be reduced to safe levels by subsequent flushing and that the structural integrity and performance of the dialyzer are not significantly affected adversely. Each chemical must be removed before the next is added, unless mixing is known to be safe and effective for reprocessing. A cleaning agent, such as sodium hypochlorite, must be cleared before adding formaldehyde in order to avoid noxious fumes and degradation of disinfectant. Combining sodium hypochlorite and peracetic acid may produce hydrochloric acid vapors.	Survey Procedures: §405.2150(a)(1) Observe the cleaning process. Many facilities use sodium hypochlorite in this step. Exposure of membranes to this solution must be limited in time to avoid damage to the membrane. If the end caps of the dialyzer ("headers") are removed during reprocessing, facility staff must ensure that the O-ring is exposed to germicide before it is reseated in the cap. Observe this process carefully and ensure that the end caps are replaced on the dialyzer from which they were removed. Failure to tighten end caps sufficiently can result in blood leaks during treatment.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
V338	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** 11.3 Performance measurements 11.3.1 Performance test after each use *In vitro* clearance of a small molecule such as sodium or urea or a comparable clearance, should be used as the actual reject criterion unless there is a strong correlation between clearance and another measurement. If clearance is used, a 10 percent loss is acceptable. Total cell volume (TCV) may be used for hollow-fiber dialyzers. The acceptable TCV is at least 80 percent of the original TCV.	**AAMI Rationale for the Development and Provision of this Recommended Practice** (11.3) Performance measurements - As dialysis facilities have attempted to rigidly comply with the 1986 edition of this recommended practice due to adoption of this document by HCFA, some have misunderstood or expressed concern about the "validation" for indirect measures such as total cell volume (TCV) as indicators of performance of reprocessed dialyzers. *In vitro* clearances require special measures and may expose the hemodialyzer to additional risks. *In vivo* clearances are subject to multiple confounding variables. In view of these misunderstandings and concerns, the emphasis of this requirement has been changed. The essential function of the hemodialyzer is mass transfer adequate to provide the prescribed care to the patient. Change in TCV has been documented in the medical literature (Deane, 1981) as an indirect measurement having a close relationship to the retained mass transfer of small molecules by the hemodialyzer performance. An integral component of the ongoing verification of the proper performance of the hemodialyzer is the monitoring requirement of section 13.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		AAMI Rationale for the Development and Provision of this Recommended Practice (11.3.1) - Performance test after each use - A measure of solute transport of the hemodialyzer, clearance must be maintained within acceptable limits to ensure that dialysis is adequate to prevent uremic complication. Because of the established clinical importance of lower molecular weight clearance (Lowrie, 1981), the committee decided that the urea clearance should be the recommended criterion for rejecting a dialyzer. The alternative of sodium clearance was included since sodium and urea clearance are similar and the former may be more easily accomplished. The committee agreed that an acceptable tolerance for urea or sodium clearance is +/- 10 percent because this amount of variation does not result in a clinically significant change in the BUN of the patient. The committee considered a proposal to include vitamin B_{12} clearance as a criterion for rejection. The committee recognizes that the clearance of larger molecules may be affected by the type of reuse cycle used, especially the cleaning agent. It was felt beyond the scope of this document to define this effect for all combinations of reuse cycles and dialyzer types. The committee recognizes that larger molecule clearances, such as that for vitamin B_{12}, are largely membrane limited (Collins and Ramirez, 1979; Dorson, et al., 1983) as opposed to small molecule clearances, such as that for urea, which are largely flow-rate limited. Larger molecule clearances will therefore be disproportionately decreased by loss of membrane area or increased membrane resistance due to protein coating of the membrane (Pizziconi, 1985). It was decided not to include vitamin B_{12} clearance as a rejection criterion because of: (a) uncertainty about the significance of protein coating of the membrane in reprocessed hemodialyzers (Gotch, 1985); (b) lack of evidence supporting the clinical relevance of vitamin B_{12} clearance when the change in clearance is within that observed with reprocessed dialyzers; and (c) extensive experience demonstrating the safety of either monitoring urea clearance or using an appropriate indirect test for the urea clearance (Deane and Bemis, 1981). Although direct clearance measurements fulfill these needs, determining the clearance for each hemodialyzer reprocessed may be impractical; moreover, there are indirect tests that reflect the mass transfer characteristics of the device which may be used in lieu of clearance measurements. The residual TCV of hollow-fiber hemodialzyers, the most widely used indirect test for clearance, has been found to yield mortality and morbidity results as good or better than those for dialyzers that have not been reprocessed in studies that do not include randomized, controlled trials (Deane & Bemis, 1981).

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		AAMI Rationale for the Development and Provision of this Recommended Practice (11.3.1) - Performance test after each use (Cont.)- - This method has been shown to be a good index to monitor the solute transport capacity of the reprocessed hollow-fiber hemodialyzer (Gotch, 1985). The volume of a hollow-fiber hemodialyzer (TCV) is readily measured in the clinical setting. Using certain methods of reprocessing that do not cause a significant change in the permeability or geometry of the membrane, a loss of TCV of 20 percent corresponds to a loss of urea clearance of less than 10 percent (Gotch, January 1984). The committee decided not to use this as the only criterion, however, since certain methods of reprocessing could conceivably change this relationship (Pizziconi, 1985). At present, volume change is recommended as a QC test only for hollow-fiber hemodialyzers because other hemodialyzers do not have the relatively noncompliant blood compartment necessary for the validity of this measurement in predicting solute transport. The question of the appropriate volume to use as the reference TCV has been asked many times. The answer is not quite as clear as it might seem. Each hemodialyzer manufacturer supplies information regarding the total blood volume. However, the techniques used by hemodialyzer manufacturers are often quite different from those employed during hemodialyzer reuse and may yield somewhat different results. For instance, several manufacturers measure the volume using kerosene, a liquid that does not "wet" the membrane. The TCV of dialyzers can vary from the values used to develop the original manufacturer's literature, from lot to lot, and from hemodialyzer to hemodialyzer within a lot. In general, these variations are of little consequence in providing the proper transport properties designed into the hemodialyzer. When the hollow-fiber diameter decreases, the internal volume and surface area also decrease. While it might appear that this would cause lower urea clearance, it does not. The shorter diffusion distances of the smaller fiber diameter causes an increase in urea transport rate, offsetting the loss in surface area. Following similar scientific principals, when individual fibers become plugged as the hemodialyzer is repeatedly used, the surface area associated with those plugged fibers is lost to solute transport and overall clearance decreases. This loss in transport is not linear because the (now) higher velocity in the remaining fibers causes an increase in the diffusion rate inside the fiber. This is the reason that a 20 percent loss in surface area only yields about a 10 percent loss in urea clearance. Therefore, what is important in the reuse setting is the loss in TCV relative to the original volume of the hemodialyzer.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		AAMI Rationale for the Development and Provision of this Recommended Practice (11.3.1) Performance test after each use (Cont.)- -The committee recommends that, whenever possible, the user measure the original volume of each hemodialyzer prior to the first patient use and record this value as the reference TCV (reprocessing volume) for all subsequent reprocessing. It is also recognized that this is not always practical. In the absence of preprocessing volume measurement for an individual hemodialyzer, the user should use the calculated average preprocessing volume for that hemodialyzer model. The average preprocessing volume can be determined by averaging the preprocessing volume of approximately 10 dialyzers (or 20 percent of the monthly usage of dialyzers, whichever is less) for each hemodialyzer model. This should be rechecked monthly. Substantial changes in average preprocessing volume should be investigated. It is recognized by the committee that other factors can influence the effective clearance of toxins during the dialysis session or interpretation of the results. These factors include: a) fistula recirculation; b) accurate blood and dialysate flow rate; c) accurate time of dialysis; d) compliance with dietary limitations; e) selection of appropriate hemodialyzer type, blood and dialysate flow; f) membrane surface coating that may affect higher molecular weight toxins; g) variations in the original clearance and K_{uf} of the hemodialyzer; h) variations in the clearance and K_{uf} of the hemodialyzer due to reuse. A proposed indirect measure of solute clearance, other than changes in TCV, is the *in vitro* ultrafiltration coefficient of the hemodialyzer (K_{uf}), or its inverse, the membrane hydraulic resistance (R_m) (Pizziconi, 1985). Unlike TCV, measurement of K_{uf} is purported to detect changes in membrane resistance as well as changes in surface area. It has been shown, however, that the standard deviation for the regression of urea clearance vs. R_m is nearly twice that of the available data for the regression of urea clearance vs. TCV in reprocessed hollow-fiber hemodialyzers (Gotch, 1985). The clinical validity of this conclusion is a matter of controversy (Gotch and Pizziconi, personal communication). The committee recognizes that measurement of K_{uf} is potentially more sensitive for large molecule clearance than for small molecule clearance (i.e., there is a greater decline in vitamin B_{12} clearance than urea clearance for a given decrease in membrane surface area). It is also acknowledged that measurement of TCV and K_{uf} may yield overlapping information. .

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		AAMI Rationale for the Development and Provision of this Recommended Practice (11.3.1) Performance test after each use (Cont.) -- The 1986 edition of this recommended practice included language that allowed a change of 20 +/- percent in the *in vitro* K_{uf} to be used as an indirect indicator of dialyzer clearance. Due to the controversy in originally adopting this recommendation, and the fact that this technique has lost favor in actual practice, the specific recommendation was removed from this edition. However, if suitable correlation of dialyzer K_{uf} (or other appropriate test) to dialyzer clearance can be demonstrated, such techniques may be used. Of particular concern to this committee are any variation in hemodialyzer functions related to reuse procedures. While there have been documented cases (Delmez, 1989), they are very rare, especially as compared to the other factors listed above. For this reason, the committee strongly feels that the monitoring requirements of section 13 are of great importance to use in conjunction with the individual hemodialzyer measurements recommended in 11.3.2. Survey Procedures §405.2150(a)(1) Observe the performance test done for each dialyzer. For manual systems be sure the graduated cylinder is emptied completely between uses and is placed on a level surface to be read. Make sure the reading is done at eye level. Look at the charts used to determine the remaining volume; reading should correspond to the specific dialyzer being reprocessed and the initial volume of that dialyzer. If the current volume is not included in the chart available, the next lower volume should be used. For automated systems ask how the system is validated to assure the volume measurements are accurate? Each dialyzer should be compared to it's own original volume rather than a nominal value. If the dialyzer's original volume was not measured, a facility determined average for that lot number of specific dialyzers may be used.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
V339	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (11.3.2) Ultrafiltration *In vitro* ultrafiltration coefficients should not be used to predict *in vivo* results. If the expected weight loss is not achieved with the reprocessed dialyzer, the reprocessing method and all other weight removal variables should be reevaluated.	**AAMI Rationale for the Development and Provision of this Recommended Practice** (11.3.2) Ultrafiltration - Ultrafiltration rate (UFR) is the flow rate of fluid that passes through the membrane under a given pressure gradient at a given temperature. It is the product of the ultrafiltration coefficient of the hemodialyzer (K_{uf}) and the transmembrane pressure. The ultrafiltration coefficient of the hemodialyzer (K_{uf}), and thus the UFR at a given transmembrane pressure, may be affected by changes in the intrinsic permeability of the membrane, the surface area of the membrane, and the presence of hydraulically resistive deposits on the membrane. Cleaning agents such as sodium hypochlorite may affect the intrinsic water permeability of many types of dialysis membranes. *In vitro* K_{uf} is not recommended to predict *in vivo* ultrafiltration performance because the former overestimates the latter (Gotch, January 1984; Wineman, 1984) in hollow-fiber hemodialyzers. This occurs in part due to the additional hydraulic resistance of the formed elements and proteins in blood. Additionally, thrombus-occluding hollow fibers may be highly permeable to water and ultrafiltration may occur from either water passage through the occluding thrombus or retrograde flow from the unoccluded end of the fiber. These factors give a higher ultrafiltration coefficient during aqueous perfusion *in vitro,* whereas *in vivo* ultrafiltration across clotted fibers results in hemoconcentration of blood in clotted fibers to the point where osmotic pressure and hydraulic pressure drop to equal the transmembrane pressure, thus decreasing the ultrafiltration coefficient in the occluded fiber to zero. Similar data are not available for other types of dialyzers, but since clotting also occurs in these devices, it was decided that *in vitro* K_{uf} should not be recommended to predict *in vivo* ultrafiltration performance in these devices as well. The committee recognized the possibility that surface deposits can significantly affect ultrafiltration (Pizziconi, personal communication, August 1984). This subject is not included in the recommended practice because of the controversy surrounding the clinical significance of protein deposits on the membrane (see A.11.3. 1) and the lack of evidence for a significant decrease of *in vitro* K_{uf} using present-day reprocessing techniques (Gotch, January 1984; Wineman, 1984). The committee also recognized that *in vitro* K_{uf} measurements in hollow-fiber dialyzers can be used to estimate *in vivo* ultrafiltration if they are corrected for the percentage change in priming volume to reflect the amount of clotting and the normal *in vitro*-to-*in vivo* drop caused by the ultrafiltration of blood rather than protein-free solution. It was decided not to include this information in the recommended practice because of the lack of consensus on the utility of this approach. Measurement of *in vitro* ultrafiltration is temperature dependent. *In vitro* aqueous K_{uf} will change approximately 2 percent per degree centigrade. Thus, care must be taken to know the actual temperature at which the measurement is made. If the measurement temperature is not 37□C, the appropriate temperature compensation algorithm should be used to correct the reading to 37□C (see Pizziconi, 1983, for an appropriate algorithm).

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
		Survey Procedures and Probes: §405.2150(a)(1) Ask the technician how the facility monitors the dialyzer's effectiveness in removing fluid from the patient. In record review, determine if target weights are achieved routinely. Does the facility monitor achievement of target-weight as an outcome indicator in the quality assurance/quality monitoring review?
V340	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (11.3.3) Blood path integrity test A membrane integrity test such as an air pressure leak test shall be done between uses.	**AAMI Rationale for the Development and Provision of this Recommended Practice** (11.3.3) Blood path integrity test - The 1986 edition of this recommended practice did not include a blood path integrity test. Based on recommendations of CDC, the committee agreed to add such a test to the second edition of the recommended practice. This test is based on the observation that only a small amount of air leaks through wetted membranes, resulting in a pressure drop of less than 10 percent of the test pressure. A maximum allowable pressure drop is not given because of variations among test systems and dialyzers. Survey Procedures: §405.2150(a)(1) Observe leak testing. Manual systems may require that each dialyzer be tested separately.
V341	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (11.4) Germicide The rinsed and cleaned dialyzer must be treated by a process that prevents adverse effects due to microbial contamination. The blood and dialysate compartments of the dialyzer must be sterilized or subjected to high-level disinfection because an inadequate germicide will result in infection in the patient. Low-level disinfection is sufficient for the exterior of the device.	**AAMI Rationale for the Development and Provision of this Recommended Practice** (11.4) Germicide - The terms "high-level disinfectant" and "low-level disinfectant" are taken from Dr. Earl Spalding, whose system classifies a germicide as a high-level disinfectant if it inactivates all vegetative organisms in a specified, relatively short period of time (i.e., 10-30 minutes) (Spalding, 1972). This implies a destruction of pathogenic bacteria and viruses but not large numbers of bacterial spores. When exposure time is extended (i.e., 6-10 hours), the same formulation often inactivates large numbers of bacterial spores which changes the classification to a sterilant (an agent that inactivates all forms of microbial life, including spores) or a sporicide (an agent that inactivates bacterial spores---this usually means inactivation of all microbial life and therefore is synonymous with "sterilant"). An example is 2 percent activated glutaraldehyde which is used as a high-level disinfectant for exposure times of 10 to 30 minutes for certain types of medical devices; this same formulation can accomplish sterilization of other types of medical devices when the exposure time is 10 hours.

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		(11.4) Germicide (Cont.) -- A low-level disinfectant in the Spalding classification has limited activity and is not effective for bacterial spores, mycobacteria, or certain types of viruses, but is effective for other types of organisms. Low-level disinfectants are used primarily to reduce microbial contamination to a comparatively safe level. The committee is aware that the EPA regulates and registers germicides formulated as "sterilants," "sporicides," "disinfectants," and "sanitizers" and that these terms may or may not be synonymous with the Spalding classification used in this recommended practice. The EPA classification is based primarily on specific label claims as well as the intended use of the chemical germicide. The definitions for "sterilant" and "sporicide" are the same as the Spalding definitions, but the definition for "disinfectant" is not. For example, according to Spalding a disinfectant which is labeled a "hospital disinfectant" has been tested against certain species of *Salmonella, Staphylococcus* and *Pseudomonas.* If the label claims that the formulation is also mycobactericidal, then *Mycobacterium bovis* is also tested. No such differentiation is made in activity in the term "disinfectant" by the EPA. Consequently, a "high-level" disinfectant in the Spalding classification may or may not be the same formulation as an EPA "disinfectant" The EPA "sanitizer" is synonymous with "low-level disinfectant" in the Spalding classification. (Antiseptics, which are chemical germicides formulated for use on skin and tissue, should not be confused with "disinfectants," which are formulated for hard surfaces or medical devices; antiseptics are regulated by the FDA Center for Drugs and Biologics.) The EPA requires manufacturers of chemical germicides formulated as general disinfectants, hospital disinfectants and disinfectants applied in other industries (e.g., food) to test these formulations by using certain protocols for microbiological efficiency, stability, and toxicity to humans. The decision to register a disinfectant and to approve label claims is based on data provided to the EPA by the manufacturer. EPA approval differs from approval by CDRH. The FDA considers a germicide used in reprocessing of hemodialyzers a medical device and regulates the labeling of such products. The agency also relies on the testing submitted by the manufacturer. Rather than using the definitions given above, the FDA at present requires that the label indicate the organisms tested and the conditions of the tests. Survey Procedures and Probes: §405.2150(a)(1) Is the germicide used to disinfect the blood and dialysate compartments a high level disinfectant? Ask the technician what could happen to the patient if a lower concentration of germicide is used to fill the dialyzers? If the answer is not acceptable, review the training curricula content for information in this area and consider citing V309.

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V342	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (11.4.1) Interior (blood/dialysate compartment (11.4.1.1) Germicide Chemical germicides or other disinfection procedures used for disinfection of hemodialyzers must have been shown to accomplish at least high-level disinfection when tested in a variety of dialyzers artificially contaminated with appropriate microorganisms, including the highly resistant water-adapted forms. If formaldehyde is used as the sole germicidal agent, the Centers for Disease Control (CDC) recommends that a concentration of 4 percent (W/V) be used in both the blood and dialysate compartments with a minimum contact time of 24 hours at a temperature of at least 20□C; lower concentrations or shorter contact times are appropriate if equivalent results can be demonstrated under other conditions. Formaldehyde used for reprocessing dialyzers should not be cloudy. Concentrated formaldehyde stored under adverse conditions can polymerize to form paraformaldehyde, a white precipitate. Formaldehyde should be of United States Pharmacopeia (USP) or better quality. When other germicides are used, the manufacturer's instructions should be followed.	**AAMI Rationale for the Development and Provision of this Recommended Practice** (11.4.1) Interior (blood/dialysate compartment - The following discussion of germicidal agents is limited to the use of high-level germicides for reprocessing dialyzers. The option of sterilization is appropriate, if feasible, because sterilization has a greater potential for killing microorganisms. Over the years, a variety of techniques and germicides have been employed in dialyzer reuse programs, ranging from simple refrigeration to the use of quaternary ammonium compounds (which are very low-level germicides) to formaldehyde concentrations of 1 to 6 percent, glutaraldehyde solutions, solutions containing peracetic acid as the active ingredient and, more recently, heat sterilization. The reason, in part, for using formaldehyde at concentrations that are less than the sterilization cycle concentration (i.e., 8 percent for 12 hours at 20□C) is that the challenge of microorganisms is not normally composed of bacterial spores. After the hemodialyzer is removed from a patient, there are two main points at which a microbiologic risk can occur: when water is used to rinse and clean the dialyzers; and when water is used to prepare the chemical germicide used for disinfection. In each case, the water is usually treated in the dialysis center itself for purposes of preparing dialysis fluids. The water that is produced is not sterile and does contain water bacteria. Gram-negative bacteria contain LPS or bacterial endotoxin which cause pyrogen reactions in dialyzing patients if the endotoxins are introduced into the blood stream. Outbreaks of pyrogenic reactions during dialysis have ceased when steps were taken to reduce the colony count in the dialysate at the end of dialysis to less than 2000 per ml. The maximum allowable colony count in the water used for dialysis was estimated to be 200 per ml (AAMI, 1982). The committee initially recommended this limit for the water used to dilute the germicide used for reprocessing hemodialyzers as a reasonable bioburden to be controlled by the germicidal procedure. Subsequently, it was decided to add the alternative of a maximum bacterial LPS concentration of 1 ng per ml for the water used to dilute the germicide since the association of reprocessed hemodialyzers with pyrogenic reactions has been defined by the LAL test rather than culture (Petersen, et al., 1981), and since the LAL test detects both viable and nonviable bacterial contamination. The committee acknowledged the evidence for cross-reactions between certain LAL tests and cellulosic materials (Pearson, 1984) and the concern about the reproducibility of LAL tests. There is no evidence that cross-reactions apply to reprocessed hemodialyzers and, even so, patient safety would not be compromised because acceptable reprocessed hemodialyzers would be mistakenly discarded rather than excessively contaminated hemodialyzers used. The committee also recognized that the LAL test is the test specified by the USP for detecting bacterial endotoxin in water. Further, the committee believes that reliable, reproducible LAL tests are readily available.

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	If the germicide has an expiration date from the manufacturer, be sure that the chemical is not outdated. Some germicides have recommendations for maximum storage time after dilution and/or activation and before usage. If this is the case, the expiration date of the prepared germicide solution should be marked on the outside of the germicide solution container and this date should be checked at the beginning of each day, before reprocessing begins. If the temperature of the disinfection process is elevated, appropriate recording means must be employed to assure that this criterion has been met. If maximum storage temperature limitations exist, records should be maintained to document this criterion. The disinfection process must not adversely affect the integrity of the dialyzer. Germicides must be rinsed from the dialyzer to below known toxic levels within a rinse-out period established for the particular germicide (see 12.4). To prevent injury, care should be taken not to mix reactive materials such as sodium hypochlorite and formaldehyde.	(11.4.1) Interior (blood/dialysate compartment) (Cont.) -- Another group of water bacteria can constitute a hazard in a dialysis center. These are the nontuberculous mycobacteria, which are acid-fast water bacteria and, much like the gram-negative bacteria, survive and are capable of excellent growth in all water including reverse osmosis and deionized water. Nontuberculous mycobacteria do not contain lipopolysaccahrides, and their presence in dialysis fluids would not tend to pose a serious pyrogenic risk to a dialyzing patient. But unlike the gram-negative bacteria, they are considerably resistant to chemical germicides (Carson, et al., 1978). For example, they are between 10 and 100 times more resistant to free chlorine than are *Pseudomonas aeruginosa* and other common gram negative water bacteria. Some strains of nontuberculous mycobacteria studied can survive a 60-minute exposure to 2 percent alkaline glutaraldehyde. By comparison, *Pseudomonas aeruginosa* at a concentration of 10^6/ml would be inactivated within a matter of minutes. Using 8 percent formaldehyde, some strains of nontuberculous mycobacteria have survived up to 6 hours of contact at room temperature; if the challenge had been *Pseudomonas aeruginosa,* the kill rate would have been so fast that it could not have been measured. The source of nontuberculous mycobacteria in an outbreak of disease among patients dialyzed at a center in Louisiana appeared to be the water used in processing dialyzers. Laboratory studies that CDC has conducted have demonstrated that the nontuberculous mycobacteria associated with the water systems in this center can readily survive 2 percent formaldehyde after 24 hours of exposure; in other instances, some strains survived for up to 96 hours. Obviously, this is not high-level disinfection. Further laboratory studies have shown that if the concentration of formaldehyde is increased to 4 percent, none of the strains of nontuberculous mycobacteria found in the water systems of the dialysis center or, for that matter, any of the strains that CDC has stockpiled and which include extraordinarily resistant strains, survive beyond 24 hours. In another more recent outbreak of mycobacteria infections in a dialysis clinic in California (Lowry, et al., 1990), CDC also showed incomplete kill of mycobacteria in manually reprocessed high flux dialyzers using 2.5 percent Renalin®. From a conservative standpoint, one should assume that nontuberculous mycobacteria may be part of the microbiologic flora of water used for rinsing and cleaning dialyzers and for preparing aqueous chemical germicides for disinfection and sterilization. Given this assumption, a dialysis center is faced with two alternatives. It could rely entirely upon aseptic techniques throughout the reprocessing procedure, use sterile rinse water and sterile germicides (membrane-filter sterilized), and employ strict QC. Most dialysis centers in this country do not have the capability to undertake such a closed-system and complex approach.

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		(11.4.1) Interior (blood/dialysate compartment) (Cont.) -- The second option would be to either use 4 percent instead of 2 percent formaldehyde or use other chemical germicides at concentrations sufficient to produce sterility or high-level disinfection. Although good QC and QA practices and adherence to protocols would have to be maintained, this is a much simpler approach. Moreover, there appears to be a scientific basis for considering 4 percent formaldehyde at a 24-hour exposure as at least a high-level germicide process. All laboratory data acquired so far shows that 24 hours of exposure with 4 percent formaldehyde at room temperature (20□ C) inactivates high levels of all strains of nontuberculous mycobacteria that have been tested; many of the test strains are among the most resistant in the CDC collection. When 4 percent formaldehyde is used, both the dialysate and the blood compartment must be filled with this concentration to prevent its reduction as a consequence of diffusion of formaldehyde from one compartment to another or of dilution by residual rinse water retained on and in the dialyzer membranes. Dilution can be prevented by passing at least three volumes of 4 percent formaldehyde through each compartment before the dialyzer is sealed for storage. The committee decided to specify an effluent within 10 percent of the original concentration to avoid a design standard that might not be appropriate in the future. The committee limited the recommendation for 4 percent formaldehyde to processes that use formaldehyde as the sole germicide, since it is possible that combinations of germicides might give a satisfactory result with less than 4 percent formaldehyde. Concentrations of formaldehyde lower than 4 percent and a contact time shorter than 24 hours are permitted if adequate disinfection can be demonstrated, since intermediate conditions have not been tested and might on further evaluation prove to be satisfactory. The committee is aware of published information regarding the use of 1 percent formaldehyde with dialyzers stored at 40□C for 24 hours (Hakim, et al., 1985). Many dialysis facilities have adopted this procedure without resulting difficulties and this seems to be an acceptable alternative to 4 percent formaldehyde at 20□C. There is, unfortunately, no realistic procedure whereby a dialysis center can monitor the effectiveness of the disinfection procedure. Such sophisticated microbiologic tests cannot be performed in dialysis centers. Moreover, this means of verification should not be attempted because it requires the use of specialized equipment and highly trained microbiologists. Instead, a center should adhere rigidly to established protocols for QC and QA. Monthly tests for total bacteria and/or endotoxin levels in the water used to make up the germicide should be conducted. Testing of the germicide's final-use concentration should be part of the center's QC program as well as verifying that each dialyzer was filled with germicide.

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		(11.4.1) Interior (blood/dialysate compartment) (Cont.) -- The committee considered a functional reverse osmosis unit and 2 percent formaldehyde disinfection, but decided not to rely on this option, because the CDC believes that reverse osmosis water might not be adequate to control contamination by nontuberculous mycobacteria, that there is a substantial chance that these highly resistant organisms may be in the source water, and that monitoring the water for nontuberculous mycobacteria is not clinically feasible. The committee considered a recommendation that the chemical quality of the water used to dilute the germicide should be the same as the water used for making the dialysate. This was deleted because of the lack of consensus on this issue, as noted above (see 7.1). Potency testing of each batch of germicide is specifically recommended for batches of manually prepared germicides regardless of whether they are used with a manual or an automated system. Germicide solutions that are diluted online by automated machines are to be checked for concentration at least monthly. Other requirements for verification of germicide presence are contained in section 12. HCFA requires (42 CFR 405.2150) that dialyzers shall not be subjected to multiple germicide solutions due to possible combined actions of the germicides on the hemodialyzer membrane. This requirement does not apply to the original sterilization process or chemical cleaning agents that the hemodialyzer might be exposed to for short periods during the cleaning process for reuse. Certain members of the committee feel that this requirement is unnecessary if each hemodialyzer is subjected to an air pressure leak test as part of the reuse process. Survey Procedures and Probes: §405.2150(a)(1) If 4% formaldehyde is used, staff (and surveyors) must wear respirators when exposed to the germicide. If germicides other than 4% formaldehyde are used, ask if the facility has documentation that these are equivalent in germicidal action to 4% formaldehyde. Ask what concentration of germicide is required and how does the technician know this concentration is delivered? Review the manufacturer's recommendations for the germicide in use and verify that these are followed. If an incubator is used to raise the dialyzer storage temperatures, a recording thermometer should be in use to assure sufficient temperature is consistently maintained. Review records of such devices.

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		Survey Procedures and Probes: §405.2150(a)(1) (Cont.) Using a scrub brush on the ends of the dialyzer or prolonged exposure to bleach could affect the integrity of the dialyzer. Cite problems with rinse out at V366. Observe that testing verifies the absence of one chemical before a second chemical is used in the disinfection process.
V343	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (11.4.1.2) Chemical germicide diluent The water used to prepare the germicide solution should have a bacterial colony count of less than 200 per ml or a bacterial LPS concentration of less than 1 ng/ml as measured by the Limulus amebocyte lysate assay.	Survey Procedures: §405.2150(a)(1) Review cultures or LAL testing. Ask the technician where cultures of water used to dilute germicide are taken. Samples should be taken from the source used for water that is used for this purpose. If LAL testing is done in the facility, ask the technician responsible to describe performing the test. When multiple tests are run daily, test materials state a control must be run every fifth test. When tests are run once a month, as in a dialysis facility, a control should be run with each test for reliability and validity.
V344	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (11.4.1.3) Chemical germicide procedure The hemodialyzer should be filled with the germicide solution until the concentration in the hemodialyzer is at least 90 percent of the prescribed concentration. The ports of the dialyzer should be disinfected and then capped with new or disinfected caps. The caps may be disinfected with dilute bleach, with the chemical used for disinfecting the hemodialyzer, with any other germicide approved by the EPA as a disinfectant, by steam, or by ethylene oxide gas.	Survey Procedures: §405.2150(a)(1) Observe the procedure. Ask the technician how he/she determines that the concentration in the dialyzer is a least 90% of that prescribed. In manual systems, it may take as much as three compartment volumes (approximately 700-1000cc) to reach these concentrations, displacing all the rinsing solution with germicide. Review reuse logs for documentation of verification of the desired concentration of germicide. Observe the cleaning of ports and caps. Each should be exposed to a disinfectant, not just rinsed with treated water.

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V345	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (11.4.1.4) Monitoring The water used to rinse and clean dialyzers and to dilute the germicide should be tested for bacterial contamination (culture and/or pyrogen testing - see 11.2.2 and 11.4.1.2) before a reprocessing program is undertaken. After dialysis with the reprocessed hemodialyzers has begun, testing for bacterial contamination should be frequent (e.g., weekly). Less frequent testing, but not less than monthly, may be appropriate if the results are considered satisfactory.	Survey Procedures and Probes: §405.2150(a)(1) Does the facility have a requirement for periodic testing of water for its bacterial and pyrogenic content? Review results of water testing. Ask the technician where samples are taken for testing the rinsing water. How often are samples taken? What are the acceptable results? What action is taken if results are not acceptable?
V346	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (11.4.1.5) Chemical germicide concentration With reprocessing systems where each batch of germicide is manually prepared, each batch of germicide should be tested prior to use to verify the proper concentration of the germicide. When the germicide is diluted on-line, its concentration in the hemodialyzer immediately after reprocessing should be checked at least monthly for each reprocessing system. When the germicide is partially or fully diluted by the user, it is of great importance that the solution be thoroughly mixed.	Survey Procedures: §405.2150(a)(1) If germicide is mixed during your survey, observe the process. Ask the technician how he/she verifies the concentration. Failure to properly mix the solution of germicide could result in uneven delivery of desired concentration to dialyzers. Review reuse logs for documentation of verification of the germicide concentration.

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V347	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (11.4.2) Exterior The outside of the dialyzer should be soaked or wiped clean of visible blood and other foreign material, using at least a low-level germicide which is compatible with the dialyzer materials of construction. Sodium hypochlorite at a concentration of 0.05 percent is usually suitable for this purpose. Certain commercial low-level disinfectants may cause some plastics used for dialyzers to crack after repeated or prolonged exposure.	**AAMI Rationale for the Development and Provision of this Recommended Practice** (11.4.2) Exterior - Low-level germicides satisfactorily clean the exterior of the device, comparable to the degree of cleaning that a new dialyzer receives. For example, 1:100 dilution of household bleach will achieve the concentration of sodium hypochlorite specified. Survey Procedures and Probes: §405.2150(a)(1) Observe the cleaning of the exteriors of the dialyzers. If a spray bottle is used, is there contact with all surfaces of the dialyzer?
V348	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (11.5) Inspection The hemodialyzer shall be examined after reprocessing to ensure that the external surface is clean, that the dialyzer is not damaged, and that rinsing of blood has been satisfactorily completed. The dialyzer should also be aesthetically acceptable in appearance.	**AAMI Rationale for the Development and Provision of this Recommended Practice** (11.5) Inspection - The committee considered a recommendation not to accept hemodialyzers with visible clots because venous filters are not used for all hemodialyzer circuits, leading to the risk of embolization to the patient if a clot were to break loose. The committee decided to reject this proposal since the allowable clots must be small and in stagnant areas that are present during the first use of the hemodialyzer and because there is no evidence of embolization from reprocessed hemodialyzers that meet this criterion. A proposal that the number of dark, clotted fibers evident upon external inspection be limited to five was not accepted because a considerably larger number may be clotted without significant adverse effect on performance and because some authorities do not agree that this criterion is essential to an aesthetically pleasing appearance. A recommendation that hemodialyzers with a pink or brownish tint not be acceptable was also deleted because this condition is difficult to define, and glutaraldehyde disinfection results in a slight tan color of the membranes that has not been shown to impair the safety or performance of the hemodialyzer. The committee recognized that the patient should be included in the aesthetic evaluation of the hemodialyzer.

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		Survey Procedures and Probes: §405.2150(a)(1) Observe the inspection of the newly reprocessed dialyzer. These inspections should be documented in reuse logs. Observe that documentation is completed after observations are made. Ask the reuse technician to describe what he/she is looking for when inspecting reprocessed dialyzers. His/her answer should include these items. Inspect the reprocessed dialyzers -- do your observations demonstrate these requirements are met?
V349	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (11.5.1) The dialyzer jacket should be free of visible blood or other foreign material.	Survey Procedures: §405.2150(a)(1) Observe reprocessed dialyzers ready for use and stored on shelves to determine whether or not the criteria at V349 - V354 are met.
V350	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (11.5.2) There should be no leaks or cracks in the dialyzer jacket or the blood or dialysate ports.	§405.2150(a)(1)
V351	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (11.5.3) There should be no more than a few dark, clotted fibers evident on inspection of the exterior of hollow fibers.	Survey Procedures: §405.2150(a)(1) Solid streaks of clotted fibers more than ½ inch wide should be questioned.

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V352	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (11.5.4) The headers of hollow-fiber dialyzers should be free of all but small peripheral clots.	§405.2150(a)(1)
V353	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (11.5.5) Blood and dialysate ports should be capped without evidence of leakage.	Survey Procedures and Probes: §405.2150(a)(1) Does the germicide fill the dialyzer? Ask what size "air bubble" is acceptable.
V354	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (11.5.6) The label should be properly filled out and legible.	Survey Procedures: §405.2150(a)(1) Torn or illegible labels should be replaced after assuring the identification of the patient dialyzer.
V355	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (11.6) Disposition of rejected dialyzers Reprocessed dialyzers which have been rejected for failure to meet performance, inspection, or other release criteria should either be immediately discarded or be further reprocessed and subjected to the performance requirements of 11.3, 11.4, and 11.5. In the latter instance, the dialyzer must be labeled as rejected and stored in a quarantine area to preclude use until requirements are met.	Survey Procedures: §405.2150(a)(1) Ask the technician if he/she reprocesses dialyzers that initially fail criteria. Observe that "failed" dialyzers are properly labeled if not immediately discarded.

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V356	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (11.7) Storage Reprocessed dialyzers that meet the performance and inspection criteria for multiple use should be stored according to the provisions of 8.2. Prolonged storage (greater than one month) must be documented to be safe and effective.	**AAMI Rationale for the Development and Provision of this Recommended Practice** (11.7) Storage - The committee acknowledged that the selection of one month as the maximum storage period permitted without validation was arbitrary. The committee was, however, unaware of any adverse effects of storage for up to one month, and therefore felt that this was a reasonable period of time. Survey Procedures and Probes: §405.2150(a)(1) Inspect stored dialyzers. Look at dates of reprocessing; are these within storage limits set by the facility?
V357	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (12) Preparation for dialysis and testing for chemical germicides and potentially toxic residues A written procedure should be followed which renders the reprocessed dialyzer safe for subsequent use.	**AAMI Rationale for the Development and Provision of this Recommended Practice** (12) Preparation for dialysis and testing for potentially toxic residues - The committee considered methods other than direct testing of the germicide as a process control in each hemodialyzer. It was noted that some automated systems add sodium chloride to the germicide and monitor conductivity. Brilliant Blue (FD&C Blue #1) added to the germicide has also been used to confirm the presence of germicide by visual inspection. There are toxicological data supporting the safety of this method (E .Lowrie, personal communication, 30 December 1984). For the 1986 edition of this recommended practice, the committee recommended testing each hemodialyzer for the presence of germicide just before rinsing and priming. Certain germicide manufacturers recommend this procedure, and their recommendation should be followed. If each hemodialyzer is not tested for presence, then a combination of process control and sampling was considered to be adequate. By conducting the test prior to use of any of a batch of dialyzers, all dialyzers from these batches may be quarantined or released.

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		(12) Preparation for dialysis and testing for potentially toxic residues (Cont.)-- The committee recognized that a residual level of less than 3 ppm for formaldehyde is the guideline for reuse in the State of California (California Code of Regulations, Title 22 §75207). This level apparently was chosen to coincide with the sensitivity of tests that detect formaldehyde. The committee decided to recommend a maximum residual level of formaldehyde of 5 ppm for the following reasons (Gotch, 1983): (a) anti-N-like antibody formation, the only established chronic toxicity due to formaldehyde in reused dialyzers, does not occur below a residual formaldehyde level of 10 ppm (see Howell, 1972; White, 1977; Crosson, 1976); (b) the maximum daily dose of formaldehyde from dialysis is less than the California OSHA daily limit, which is based on a 5-day week, whereas dialysis patients usually dialyze three or fewer times a week (Gotch, 1984); (c) there is no evidence of toxicity due to the long-term use of methenamine by mouth for urinary tract infections at doses that release considerably more formaldehyde to the patient than comes from reused dialyzers; and (d) residual formaldehyde levels lower than 5 ppm are difficult to monitor and considerably increase the time required to prepare the dialyzer for dialysis. The committee considered establishing maximum residual levels for germicides other than formaldehyde. Consensus could not be reached on this issue because of the relative lack of experience with these agents in reprocessing hemodialyzers. It was noted that toxicology studies are favorable for some of these agents and that the labeling information for them, which includes the maximum residual level, is reviewed by the FDA. Survey Procedures: §405.2150(a)(1) Observe residue procedure. If you have reason to question what you observe, ask to review the written procedure. If you identify a deficiency, cite the practice AND cite not following the facility procedure.

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V358	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (12.1) Visual inspection The dialyzer should be inspected before preparing it for use. Completion of this inspection should be recorded in the reprocessing record (see 4.2), accompanied by the signature or other unique means of identification of the person completing the inspection. The inspection should include the following features: a) The label on the reprocessed dialyzer should be intact, affixed to the device, legible, and should contain the information recommended in 10.3; b) there should be no indication of structural damage or tampering with the dialyzer; c) the ports of the dialyzer should be properly capped; the presence of germicide in the dialysate and blood compartment, including headers, should be confirmed; and there should be no evidence of leakage from the ports or other portions of the dialyzer;	**AAMI Rationale for the Development and Provision of this Recommended Practice** (12.1) Visual inspection - See section 12 Survey Procedures and Probes: §405.2150(a)(1) Observe setup for reuse. Ask who is responsible for this visual inspection. Ask that individual what parameters they expect to see in a dialyzer they are preparing for use. How is the inspection documented? Each parameter does not have to be individually documented, however, the individual doing the work should be able to tell you each of these required parameters, and there should be a policy for this inspection which lists these parameters. Again, observe practice and interview the persons responsible; review policy if questions arise.

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	d) the duration of storage should be appropriate for the agent or method used to sterilize or disinfect the dialyzer; e) the cosmetic appearance of the dialyzer should be aesthetically acceptable.	
V359	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (12.2) Verification of patient identification Except in the case of home dialysis, two persons should check that the first and last names on the dialyzer and any other appropriate identifying information correspond to the identifying information on the patient's permanent record. If possible, one of the persons checking identification should be the patient. Completion of this step should be recorded in the reprocessing records (see 4.2), accompanied by the signature or other unique means of identification of the person verifying patient identification. *NOTE-This step may be done later in the procedure but must precede initiation of dialysis.*	**AAMI Rationale for the Development and Provision of this Recommended Practice** (12.2) Verification of patient identification - See section 12 Survey Procedures and Probes: §405.2150(a)(1) Are patients asked to verify that the reprocessed dialyzer being used is theirs? Observe the verification of patient identity with his/her dialyzer. Standard of practice is that the final check should be done when the patient has come to the treatment chair. Observe if patients check their dialyzers for their name. Ask patients if they check their dialyzer. Ask patients who sign the treatment record what their signature means.

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V360	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (12.3) Verification of germicidal contact The contact time of the germicide or disinfection procedure must comply with the facility's protocol. The presence of chemical germicide in each hemodialyzer must be assured through direct testing or on-line process and procedural control. If other disinfection procedures are employed, there must be methods to assure that each hemodialyzer has been properly subjected to the disinfection process. An individual mark should clearly identify the operator responsible for this verification.	**AAMI Rationale for the Development and Provision of this Recommended Practice** (12.3) Verification of germicidal contact - See section 12 Survey Procedures and Probes: §405.2150(a)(1) Are tests performed to verify the presence of germicide in the dialyzers during storage? Observe the procedure for verifying sufficient contact time, and the presence of germicide after storage. Ask who is responsible for documenting this verification.
V361	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (12.3.1) Time period The period of time that each hemodialyzer was filled with germicide or exposed to the disinfection process must meet or exceed the minimum time specified by a written procedure or manufacturer's recommendations.	Survey Procedures and Probes: §405.2150(a)(1) Ask the reuse technician what the minimum germicide contact time is. Inspect several dialyzers during setup or during treatment to verify that each was exposed to the disinfection process for the required time.
V362	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (12.3.2) Presence test of each hemodialyzer Certain germicide manufacturers require the testing for presence of germicide in each hemodialyzer prior to rinsing. These instructions must be followed.	Survey Procedures and Probes: §405.2150(a)(1) Ask if the manufacturer requires testing for presence. Manufacturers of peroxyacetic acid (trade name Renalin®) and glutaraldehyde (trade name Diacide®) require that every dialyzer be tested. Observe the testing.

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V363	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (12.3.3) Process control and sampling In the absence of the requirement in 12.3.2, the presence of germicide may be assured by a direct presence test of each hemodialyzer or the use of process control and sampling of the dialyzer for germicide.	§405.2150(a)(1)
V364	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (12.3.3.1) Process control a) Use hemodialyzer germicide filling equipment with on-line automatic monitors during the germicide dilution and hemodialyzer filling process; or b) Use an indicator substance, such as FD&C Blue #1 that reliably indicates the presence of germicide. If blue dye is used, it should be added to the germicide concentrate before dilution, not to the fully diluted solution. Note that the use of dye may be inappropriate with certain germicides.	Survey Procedures and Probes: §405.2150(a)(1) To verify presence of germicide, the facility must either-- 1) Test every dialyzer (V362); 2) Use on-line automatic monitors during germicide dilution and dialyzer filling; or 3) Use an indicator, such as dye. Many facilities that use formalin use a blue dye as an indicator. Blue dye can also be added to glutaraldehyde. It should not be used with Renalin®. Ask when the dye is added. The dye should be added to the concentrate.

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V365	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (12.3.3.2) Sampling a) Sample at least one hemodialyzer per patient shift per reuse system with a direct presence test (do not use a Schiff test for formaldehyde for this purpose because it will detect the presence of inadequate concentrations of formaldehyde). b) For germicide prepared in batches, sample at least one hemodialyzer from each batch with a direct presence test. c) Sampling and testing is to be accomplished before any hemodialyzers processed on this shift are used by patients.	Survey Procedures: §405.2150(a)(1) Ask if any dialyzers are tested for the presence of germicide. Observe this test. If the facility has more than one reuse cart or machine, at least one dialyzer processed on each system per patient shift must be tested. If germicide is manually diluted and mixed, determine whether at least one dialyzer from each batch is tested for presence. Observe that the testing is done before the use of any of the dialyzers that were processed on the same shift.
V366	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (12.4) Priming the dialyzer and rinsing of the germicide The dialyzer shall be rinsed and primed according to a procedure that has been documented to produce a reduction in the concentration of germicide to an acceptable level and to result in a physiological solution in the blood and dialysate compartments.	**AAMI Rationale for the Development and Provision of this Recommended Practice** (12.4) Priming the dialyzer and rinsing the germicide - See section 12 Survey Procedures: §405.2150(a)(1) Observe the rinsing procedure. Refer to the germicide manufacturer's requirements for specific rinsing procedures, which vary by germicide. Ask the person responsible to explain the rinsing and priming steps. If questions arise, review written policy.

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V367	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (12.4.1) Testing for residual germicide Residual germicide shall be measured by a test of appropriate sensitivity according to a written procedure in order to ensure that the germicide level is below the maximum recommended residual concentration. In the case of formaldehyde, the recommended maximum level is 5 ppm. Completion of this step should be documented in the reprocessing record (see 4.2), accompanied by the signature or other unique means of identification of the person performing the test. A written policy should establish the maximum allowable time between rinsing the germicide from the dialyzer and beginning dialysis.	**AAMI Rationale for the Development and Provision of this Recommended Practice** (12.4.1) Testing for residual germicide - See section 12 Survey Procedures and Probes: §405.2150(a)(1) Are test procedures used to determine the concentration of residual formaldehyde sensitive enough to assure that the 5 ppm level is not exceeded? (Clinitest® is not acceptable). Do operational logs indicate that tests have been performed? This test is frequently documented on the patient treatment record. In reviewing records, verify that the absence of residual germicide is routinely documented. Ask if there is a maximum time allowed between rinsing the germicide and beginning dialysis.
V368	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (12.4.2) Repeat of germicide removal and testing steps if required Certain germicides have been demonstrated to disperse into solid components or less rapidly exchangeable compartments of the hemodialyzer. The priming, removal, and residual testing process should be reinstituted after a delay sufficient to bring concentrations of germicide above the recommended level (rebound). Additional rinsing should be performed to yield a germicide level below the maximum recommended concentration prior to the initiation of dialysis. The rinse procedure should be documented step by step, and all personnel should be familiar with it and follow it.	**AAMI Rationale for the Development and Provision of this Recommended Practice** (12.4.2) Repeat of germicide removal and testing steps if required - A number of procedural steps have been identified that, if not followed, may cause residual germicide to remain in the hemodialyzer following rinsing. The following list, while not all-inclusive, should be carefully considered when developing the facility's rinsing procedure: a) Air bubbles in the fibers can cause individual fibers to become blocked. Be sure that the arterial line is fully primed before connection to the hemodialyzer. If peracetic acid-type germicide is used, be sure the blood side is flushed before beginning dialysate flow. b) Air trapped in the dialysate side of the hemodialyzer may cause germicide to also remain trapped in portions of the hemodialyzer. Rotate the hemodialyzer during the rinsing process. This action normally will release the trapped air and allow the germicide to be fully rinsed. c) Germicide may back up into the heparin or monitor lines. Be sure that the heparin line is clamped and fluid is not forced into the monitor lines.

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		(12.4.2) Repeat of germicide removal and testing steps if required (Cont.)-- d) Germicide may back up into the saline bag during the rinsing procedure. Be sure that your procedure accounts for all situations that may force fluid from the dialysis circuit back into the saline bag. e) Care must be taken to avoid a false negative residual disinfection test by sampling too quickly after a quantity of saline has been infused. Equilibration must take place before sampling. f) Discard the prime solution when beginning blood flow to the hemodialyzer. Do not connect the venous line to the venous needle until blood has reached the venous bloodline. Survey Procedures: §405.2150(a)(1) Ask the individual responsible for setup to explain "rebound." This explanation should include the possibility that germicide levels could increase if fluid circulating through the dialyzer is stopped before treatment is initiated. The rebound effect could expose a patient to germicide. If rinsing and priming are interrupted, retesting for residual germicide must be done before patient treatment is started.
V369	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (12.5) Written procedure for tests for germicide or other residues There shall be a written procedure for all tests employed in preparing the dialyzer for use, including mention of each test's sensitivity. Any alterations in the procedures shall be approved by the physician in charge of the reuse program.	Survey Procedures: §405.2150(a)(1) Review written procedures for any area of the process you question. If personnel are not following the written procedure, ask to see the physician's approval for the modification in procedure.

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V370	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (13) Monitoring (13.1) Dialysis The clinical course of the patient should be observed and recorded during each dialysis to identify possible complications due to new or reprocessed dialyzers. Dialyzer failures should be recorded and systematically evaluated. Home dialysis patients, and/or their assistants should be instructed in the appropriate observations, recording, and reporting procedures.	Survey Procedures and Probes: §405.2150(a)(1) Do patient records indicate whether patients are being treated with new or reprocessed dialyzers? Review patient records for intradialytic monitoring. Ask how often vital signs are checked; do records verify stated policy is followed? Are dialyzer failures (leaks, failure to remove fluid) documented and reviewed for trends? Does documentation reflect adverse reactions, e.g., febrile reactions, signs of infection or chemical reactions? Interview home dialysis patients (and/or their assistants). Is reuse being done in the home? What kind of reuse training is given? Is there evidence of review of reuse in the home by staff on some periodic basis? Has the home patient been educated about the possible complications associated with new or reused dialyzers? Check the patient's adequacy, hematocrit level, and any pattern of infection as these indicators can be influenced by reuse.
V371	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (13.2) Symptoms (13.2.1) Fever and chills Temperature should be measured and recorded at least before and after dialysis with new and reprocessed dialyzers. A temperature of over 37.8□C (100□F), taken orally, or chills should be reported to the physician. Unexplained fever and/or chills occurring more often than just during dialysis with new dialyzers should be promptly evaluated for endotoxin contamination of the water used for reprocessing (see 11.2.2 and 11.4.1.2) and of the sterilization or disinfection process (see 11.4 and table 2).	**AAMI Rationale for the Development and Provisions of this Recommended Practice** (13.2) Symptoms - Evaluation by a physician is required to determine whether symptoms might constitute an adverse reaction to the reprocessed dialyzer because symptoms during dialysis are commonly due to other factors such as infections not attributable to dialysis and to hypovolemia. **Table 2 - Patient safety** Patient health effect — Probable underlying cause Infection — Improperly used or selected germicide or method; contamination or break in sterile procedure during dialyzer rinsing, priming, or set-up Pyrogen reactions, endotoxemia — Improper processing technique, contaminated water used to rinse dialyzers or to prepare germicide solutions Acute chemical reactions — Inadequate dialyzer preparation and priming procedures

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		Survey Procedures and Probes: §405.2150(a)(1) Observe that temperatures are taken before and after treatment; not after treatment is started or before treatment ends. When reviewing treatment records, note that temperatures are recorded and action taken for elevated temperatures or chills. Interview patients to determine whether they have experienced reactions with reused dialyzers
V372	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (13.2.2) Other symptoms Other unexplained symptoms, such as pain in the blood-access arm at the onset of dialysis, should be evaluated by the physician and consideration given to the possibility that the symptom may be attributed to the new or reprocessed dialyzer. Suspected reactions to the residual germicide should prompt reevaluation of the rinsing procedure and test for residual germicide (see 12.4.1 and 12.4.2 and table 2).	Survey Procedures and Probes: §405.2150(a)(1) During patient interviews, ask if the patient has ever experienced pain in the access area at the start of dialysis.

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V373	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (13.2.3) Recording Any significant events such as the symptoms listed above should be recorded on an incident report form which includes the results of any evaluations conducted by the physician and others and reported to the manufacturers in accordance with the Safe Medical Devices Act of 1990. The resolution of actual or suspected problems caused by reprocessed dialyzers should be indicated. This form should be kept in the complaint investigation record file (see 4.5).	Survey Procedures and Probes: §405.2150(a)(1) Review the complaint file. Ask the chief technician or Director of Nursing what procedures are in place to comply with the Safe Medical Devices Act of 1990. Review incident and accident forms concerning reuse as part of your review of the facility's quality assurance program.
V374	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (13.3) Dialyzer failures Dialyzer blood leaks or excessive deviations from the expected ultrafiltration (weight loss) should be recorded in a log kept in the complaint investigation file (see 4.5). If there is excessive deviation from the expected ultrafiltration, testing should be repeated (see 11.3.2) and appropriate adjustments made in the reprocessing procedure or the algorithm for estimating the expected ultrafiltration.	**AAMI Rationale for the Development and Provisions of this Recommended Practice** (13.3) Dialyzer failures - This section sets up conditions under which some of the tests given in section 11 should be conducted. The option of adjusting the algorithm for ultrafiltration (UFR) refers to a significant change of UFR without a significant change of clearance. Survey Procedures and Probes: §405.2150(a)(1) Ask the charge nurses how they monitor the actual vs. expected weight removal. Ask what action would be taken if the desired weight loss was consistently not achieved.

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	Deterioration of a patient's clinical condition or variability of routine dialysis procedures (heparinization, ultrafiltration, transfusion requirement) require investigation of all practices, including reuse. Reports of investigations should be filed in the complaint log. A progressive, otherwise unexplained rise in serum creatinine should also be recorded in the complaint investigation file and properly investigated.	Survey Procedures and Probes: §405.2150(a)(1) (Cont.)-- In reviewing Quality Management materials, are deviations from expected ultrafiltration or failures to achieve dialysis adequacy targets evaluated? If such failures are not corrected by changes in treatment, the function of the reuse system must be evaluated.
V375	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (13.4) Clinical results In order to assure that all parameters relating to hemodialyzer clearance are being met, monitoring of relevant patient results is recommended. Specifically, regularly sequential pre- and post-dialysis blood urea nitrogen (BUN) ratios (or formal urea kinetic modeling studies) should be done. The failure of these results to meet the expectations of the dialysis prescription should be investigated.	**AAMI Rationale for the Development and Provisions of this Recommended Practice** (13.4) Clinical results - Critical assessment of chemistries, as are done monthly, provides a clear trend line to assess treatment. This scrutiny of the patient's treatment and course is the primary confirmation that hemodialyzer performance anticipated from total cell volume or other indirect estimation is accurate and adequate. Instead of measuring only the clearance of the dialyzers, the overall effectiveness of the entire treatment is measured. No other measure of the effectiveness of new or reused dialyzers is as clear or relevant. Trend lines developed from these data characterize the quality of therapy. Information concerning protein intake and catabolic rate may be necessary because of their effect on blood urea nitrogen concentration. Other professional assessments of patient well-being should be considered. If the practitioner has concerns for "middle molecules" or other clinical parameters, these factors should also be part of the assessment of the delivered therapy. There are many reasons for an apparent reduction in the mass transfer of urea, other than decreased hemodialyzer clearance as a result of inadequate reprocessing (such as recirculation, decreased dialysis time or blood flow rate, or an inappropriate dialysis prescription). In order to document adequate mass transfer, parallel measurements of pre- and post-creatinines may be helpful. When problems develop with any patient or group of patients, monitoring intensity must be increased and other methods used to analyze the problem and define corrective action. Techniques to compare survival among facilities and for individual facilities against national and regional standard mortality rates are an important instrument for a facility to use in self-assessment (Wolfe, 1992). The committee recommends periodic review of this outcome measure.

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		Survey Procedures and Probes: §405.2150(a)(1) Ask a staff member where you would find the Urea Reduction Ratio (URR) or kinetic modeling (Kt/V) studies/reports. Review this data. Monthly measurement of these adequacy indicators is recommended. Ask the nurse director or medical director for the facility's adequacy target number; verify that this target is within current professional practice guidelines (available from the ESRD Network offices or ESRD professional literature). When individual patients do not meet the facility target for adequacy, what action is taken, i.e., increased treatment time, increased size of dialyzer, increased blood flow rate, check access flow rate?
V376	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (14) Quality Assurance It is the responsibility of all staff to carry out critical scrutiny of all materials, practices, operation, and outcomes. Criteria that serve as the scale for evaluation may be drawn from local experience and practice relative to the specific activity under review, from consensus documents such as AAMI guidelines or standards, from aggregated regional or national data, or from other accepted norms. The criteria chosen as the internal standards of a facility must be documented in its policy and/or procedure manual. Process review should be part of the activity of the individual carrying out the process, and oversight of that review by another qualified member of the staff or a group of staff should affirm, modify, or repeat these observations to confirm or improve the process. Clinical outcomes serve as the most important indicator of quality of all reuse processes.	**AAMI Rationale for the Development and Provisions of this Recommended Practice** (14) Quality assurance - The FDA's 1987 compliance policy guide (7124.16) advises reuse practitioners to establish: (a) adequate device cleaning and sterilization; (b) the lack of adverse effects on device quality or physical characteristics; and (c) that the device remains safe, reliable, and effective for its intended use. The committee believes that compliance with these recommendations necessitates use of regularly examined reprocessing procedures based on methods of demonstrated effectiveness carried out under conditions safe to the patient and to the personnel. Survey Procedures and Probes: §405.2150(a)(1) Ask responsible staff what criteria are used to evaluate the quality of the reuse program. Who is responsible for process review? How often is the reuse process observed by another member of the staff?

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V377	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (14.1) Records A record of review, comments, trend analysis, and conclusions arising from quality assurance (QA) practices will serve as a foundation for future review and as documentation to external evaluation.	Survey Procedures and Probes: §405.2150(a)(1) Do Quality Management meeting minutes document review of the reuse practices?
V378	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (14.2) Schedule of quality assurance activities Problems in a particular aspect of operations should be reviewed and followed up until a solution is in place and demonstrated to be effective. High volume tasks of recognized hazard should have frequent (weekly or daily) oversight. Practices with little potential for harm may only need critical scrutiny on a quarterly or annual basis. The medical director is responsible for the schedule of review, endorsement of findings, and, where appropriate, implementation of changes.	Survey Procedures and Probes: §405.2150(a)(1) Ask to review the schedule of reuse quality assurance activities. The frequency of various activities should meet the requirements of AAMI sections 14.2 through 14.9.
V379	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (14.3) Patient considerations Personnel should audit compliance with policy for informed consent at least annually.	Survey Procedures: §405.2150(a)(1) If consent for reuse is required by facility policy, these consents should be reviewed annually.

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V380	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (14.4) Equipment Designated staff should audit written procedures and manuals for relevance at least annually and whenever adverse findings could be attributed to equipment failure. Designated staff should also audit maintenance and repair policies at least annually. At least twice a year, designated staff should verify the testing procedures recommended in 7.1.1, 7.1.2, and 7.2.2.	Survey Procedures and Probes: §405.2150(a)(1) If you identify a problem in the reuse practice, ask to review that policy. If there is a question regarding the policy, verify that policies are reviewed annually. If problems in disinfection (AAMI requirement 7.1.1), water quality (AAMI requirement 7.1.2) or process control (AAMI requirement 7.1.2) are identified, verify that these areas are tested at least twice a year.
V381	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (14.5) Physical plant and environmental safety considerations Designated staff should audit the provisions of 8.1 through 8.3 at least annually. The provisions of 8.2 should be audited at least quarterly. Designated staff should verify the tests specified in 8.3 at least quarterly.	Interpretive Guidelines: §405.2150(a)(1) 8.1: Requires ventilation of reuse area 8.2: Requires segregation of new, used and reprocessed dialyzers and rotation of stock 8.3: Requires tests for germicide levels

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V382	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (14.6) Reprocessing supplies Designated staff should audit the provisions of section 9 at least semiannually.	Interpretive Guidelines: §405.2150(a)(1) Section 9 addresses testing of germicide quality and rotation of stock.
V383	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (14.7) Hemodialyzer labeling The provisions of section 10 should be audited by designated staff at least quarterly.	Interpretive Guidelines: §405.2150(a)(1) Quality Management materials should document audits of dialyzer labeling requirements at least quarterly.
V384	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (14.8) Reprocessing Designated staff should audit the written procedures for the various steps in this process and verify implementation, at least monthly to begin with. Semiannual audits may be sufficient, based on a documented history of favorable results. Designated staff should perform the necessary testing specified in section 11. Trend analysis should be done.	Survey Procedures: §405.2150(a)(1) If this is the first resurvey at this facility, verify monthly audits were performed initially until all staff were noted to be error free. Quality Management materials should document these audits and include analysis of any trends.

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V385	**AAMI Requirements as Adopted by Reference 42 CFR 405.2150(a)(1)** (14.9) Preparation for dialysis Designated personnel should audit the written procedures and verify their implementation at least quarterly. Designated staff should verify the tests for the presence of germicide and the test for residual germicide by using positive and negative control solutions at least quarterly. *End AAMI Requirements*	Survey Procedures and Probes: §405.2150(a)(1) Do quarterly audits document that an objective observer verifies competence of the reuse technicians to follow policy? Ask the reuse technician for documentation of the positive and negative controls for the tests for presence and for residual germicide.
V386	§405.2150(a) (2) Procedure for chemical germicides. To prevent any risk of dialyzer membrane leaks due to the combined action of different chemical germicides, dialyzers are exposed to only one chemical germicide during the reprocessing procedure. If a dialyzer is exposed to a second germicide, the dialyzer must be discarded.	Interpretive Guidelines: §405.2150(a)(2) This requirement is intended to mean long time exposure to a disinfectant that is used during the storage of the dialyzer rather than a short exposure to chemicals used during the rinsing process. This requirement excludes the use of chlorine bleach in conjunction with another germicide. If the facility changes disinfectants, the dialyzers that were used with the original disinfectant should be discarded before instituting reprocessing with the new germicide.

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V387	(3) Surveillance of patient reactions. In order to detect bacteremia and to maintain patient safety when unexplained events occur, the facility- (i) Takes appropriate blood cultures at the time of a febrile response in a patient; and	Survey Procedures and Probes: §405.2150(a)(3)(i) How and when are blood cultures taken? Do patient interviews/record reviews confirm that cultures are collected when indicated? Does the facility policy and practice allow the nursing staff to collect blood cultures in the event of a febrile response without requiring an individualized physician order?
	(ii) If pyrogenic reactions, bacteremia, or unexplained reactions associated with ineffective reprocessing are identified, terminates reuse of hemodialyzers in that setting and does not continue reuse until the entire reprocessing system has been evaluated.	Interpretive Guidelines: §405.2150(a)(3)(ii) An unexplained rise in the patient's serum creatinine, which may result from an improperly cleaned dialyzer, should be investigated immediately by the facility.
V388	(b) Standard: Transducer filters. To control the spread of hepatitis, transducer filters are changed after each dialysis treatment and are not reused.	Interpretive Guidelines: §405.2150(b) Transducer filters are devices used in the extra corporeal blood circuit to prevent blood from contacting the transducer sensors. These filters must be replaced each time a new patient uses the machine whether the facility practices reuse or not. These filters should also be changed whenever they become wet. A wet external filter would not protect the internal filter from contamination. Survey Procedures and Probes: §405.2150(b) Observe that transducer filters are changed when wetted and between each patient treatment.

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V389	(c) Standard: Bloodlines. If the ESRD facility reuses bloodlines, it must-- (1) Limit the reuse of bloodlines to the same patient;	Interpretive Guidelines: §405.2150(c) If this standard is not met, see probe at V300 regarding additional information needed for the regional office to determine appropriateness of denial of payment and/or termination. Interpretive Guidelines: §405.2150(c)(1) The labeling must uniquely identify the patient who is using the bloodline. The bloodline should be labeled with other information essential to proper reuse procedure, and should be updated after each use.
V390	(2) Not reuse bloodlines labeled for "single use only";	Interpretive Guidelines: §405.2150(c)(2) Facilities usually only reuse arterial lines. They do not reuse venous lines.

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V391	(3) Reuse only bloodlines for which the manufacturer's protocol for reuse has been accepted by the Food and Drug Administration (FDA) pursuant to the premarket notification (section 510(k)) provision of the Food, Drug, and Cosmetic Act.	Interpretive Guidelines: §405.2150(c)(3) Facilities reprocessing blood lines must follow the protocols described in the manufacturer's labeling. If the manufacturer's protocols permit, blood lines may be reprocessed separately, however, they should be appropriately labeled with the patient's name or other identifying designation and the facility should provide a written protocol for this procedure. Survey Procedures and Probes: §405.2150(c)(3) Obtain a copy of the reprocessing protocols for the bloodline being used by the facility. It must correspond with the protocols being used. The facility must follow an FDA-approved protocol and may only reprocess lines specified by that protocol.
V392	(4) Follow the FDA-accepted manufacturer's protocol for reuse of that bloodline.	Survey Procedures: §405.2150(c)(4) Using a copy of the accepted manufacturer's protocol as guidance, observe the facility's reprocessing practice and review the reprocessing records. If your review and/or observation detects that the protocol is not being followed, cite a deficiency regarding those aspects of the protocol that are not being followed. For example, should the protocol require the exposure of a specific dilution of a disinfectant for a specific period of time and this protocol is not being followed, enter the finding as a deficiency in the Automated Survey Processing Environment (ASPEN) program.

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V410	§405.2160 Condition: Affiliation agreement or arrangement. (a) A renal dialysis facility and a renal dialysis center (see §405.2102(e)(2)) have in effect an affiliation agreement with each other, in writing, for the provision of inpatient care and other hospital services.	§405.2160(a)
V411	(b) The affiliation agreement or arrangement provides the basis for effective working relationships under which inpatient hospital care or other hospital services are available promptly to the dialysis facility's patients when needed. The dialysis facility has in its file documentation from the renal dialysis center to the effect that patients from the dialysis facility will be accepted and treated in emergencies. There are reasonable assurances that:	Interpretive Guidelines: §405.2160(b) Hospitals qualified as renal dialysis centers (RDC) have a specific provider number for this service in addition to the hospital's number as a provider under the conditions of participation for hospitals. The dialysis facility should have a written agreement with a hospital that can provide acute care to meet the needs of an ESRD patient. These hospitals should provide dialysis service as well as adequate laboratory, social, and dietetic services to ESRD patients. (Refer to 9/25/97 memorandum). Survey Procedures and Probes: §405.2160(b) A required hospital-type service not offered by the ESRD facility on its premises should be provided through an affiliation or arrangement (see §405.2102) with a hospital that can provide acute care to meet the needs of an ESRD patient. Is there an agreement in place with a hospital so that when a dialysis facility patient requires hospital services, e.g., surgery, emergency treatment, access to acute dialysis service, it is available while hospitalized?

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V412	(1) Transfer or referral of patients will be effected between the renal dialysis center and the dialysis facility whenever such transfer or referral is determined as medically appropriate by the attending physician, with timely acceptance and admission;	§405.2160(b)(1)
V413	(2) There will be interchange, within 1 working day, of the patient long-term program and patient care plan, and of medical and other information necessary or useful in the care and treatment of patients transferred or referred between the facilities, or in determining whether such patients can be adequately cared for otherwise than in either of such facilities; and	§405.2160(b)(2)

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V414	(3) Security and accountability for patients' personal effects are assured.	§405.2160(b)(3)
V420	§405.2161 Condition: Director of a renal dialysis facility or renal dialysis center. Treatment is under the general supervision of a Director who is a physician. The physician-director need not devote full time as Director but is responsible for planning, organizing, conducting, and directing the professional ESRD services and must devote sufficient time to carrying out these responsibilities. The director may also serve as the Chief Executive Officer of the facility.	§405.2161

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V421	(a) Standard: Qualifications. The director of a dialysis facility is a qualified physician director. (See §405.2102.)	Interpretive Guidelines: §405.2161(a) A "qualified physician director" is defined by §405.2102 as a physician who: (1) Is board-eligible or board-certified in internal medicine or pediatrics by a professional board, and has had at least 12 months of experience or training in the care of patients at ESRD facilities; or (2) During the 5 year period prior to September 1, 1976, served for at least 12 months as director of a dialysis or transplantation program;or (3) In those areas where a physician who meets the definition in paragraph (1) or (2) here is not available to direct a participating dialysis facility, another physician may direct the facility, subject to the approval of the Secretary.
V422	(b) Standard: Responsibilities. The responsibilities of the physician-director include but are not limited to the following: (1) Participating in the selection of a suitable treatment modality, i.e., transplantation or dialysis, and dialysis setting, for all patients;	§405.2161(b)(1)
V423	(2) Assuring adequate training of nurses and technicians in dialysis techniques;	Survey Procedures and Probes: §405.2161(b)(2) What evidence is there to show that the physician-director is involved in ensuring that the staff are adequately trained in the dialysis techniques used in the facility? If the staff demonstrate that they have not been adequately trained, the physician-director is accountable and deficiencies should be cited here.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
V424	(3) Assuring adequate monitoring of the patient and the dialysis process, including, for self-dialysis patients, assuring periodic assessment of patient performance of dialysis tasks;	Survey Procedures and Probes: §405.2161(b)(3) Determine the minimum monitoring requirements in the facility as developed by policy. If this is less frequent than hourly, ask the staff to explain the policy and procedures for monitoring. Review treatment worksheets to ensure that the policy is met. When patients demonstrate changes, such as a drop in blood pressure, more frequent monitoring to evaluate treatment should be done. This should be noted in the treatment worksheets. Determine which pre/post assessments are required and documented. At a minimum, fluid status (heart and lung sounds, presence/absence of edema) and condition of the access should be documented.
V425	(4) Assuring the development and availability of a patient care policy and procedures manual and its implementation. As a minimum, the manual describes the types of dialysis used in the facility and the procedures followed in performance of such dialysis; hepatitis prevention and procedures for handling an individual with hepatitis; and a disaster preparedness plan (e.g., patient emergency, fire, flood); and	§405.2161(b)(4)
V426	(5) When self-dialysis training is offered, assuring that patient teaching materials are available for the use of all trainees during training and at times other than during the dialysis procedure.	§405.2161(b)(5)
V430	§405.2162 Condition: Staff of a renal dialysis facility or renal dialysis center. Properly trained personnel are present in adequate numbers to meet the needs of the patients, including those arising from medical and nonmedical emergencies.	§405.2162

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
V431	(a) Standard: Registered nurse. The dialysis facility employs at least one full time qualified nurse responsible for nursing service. (See §405.2102.)	Interpretive Guidelines; §405.2162(a) A "nurse responsible for nursing service" as defined in §405.2102 is a person who is licensed as a registered nurse by the State in which practicing, and (1) Has at least 12 months of experience in clinical nursing, and an additional 6 months of experience in nursing care of the patient with permanent kidney failure or undergoing kidney transplantation, including training in and experience with the dialysis process; or (2) Has 18 months of experience in nursing care of the patient on maintenance dialysis, or in nursing care of the patient with a kidney transplant, including training in and experience with the dialysis process; (3) If the nurse responsible for nursing service is in charge of self-care dialysis training, at least 3 months of the total required ESRD experience is in training patients in self care. "Full time" means employed 40 hours/week by the facility or for the number of hours the facility is open, whichever is less. One nurse could be employed full time at two facilities if one was open Monday/Wednesday/Friday and the second was open Tuesday/Thursday/Saturday. A single RN could not be considered full time by 3 or more facilities.
V432	(b) Standard: On-duty personnel. Whenever patients are undergoing dialysis: (1) One currently licensed health professional (e.g., physician, registered nurse, or licensed practical nurse) experienced in rendering ESRD care is on duty to oversee ESRD patient care:	Interpretive Guidelines: §405.2162(b)(1) If the facility policy/practice does not mandate that a registered nurse be present at all times of treatment, be sure that all necessary care, such as CPR and administration of intravenous medications, can be delivered by the licensed person on duty. If State law requires a registered nurse or physician to administer emergency intravenous medications, then such a person must be present during dialysis treatments.
V433	(2) An adequate number of personnel are present so that the patient/staff ratio is appropriate to the level of dialysis care being given and meets the needs of patients; and	Survey Procedures and Probes: §405.2162(b)(2) Facility policy should define appropriate patient/staff ratios. Compare staffing records with this policy. Review records for evidence that qualified staff perform assessments and respond to patient emergencies.
V434	(3) An adequate number of personnel are readily available to meet medical and	§405.2162(b)(3)
V435	nonmedical needs.	§405.2162(b)(3)

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
V436	(c) Standard: Self-care dialysis training personnel. If the facility offers self-care dialysis training, a qualified nurse is in charge of such training (See §405.2102.)	Interpretive Guidelines: §405.2162(c) A "qualified nurse" (See guidelines at V431 for a "nurse responsible for nursing service") must be in charge of self-dialysis training, if that service is offered by the facility. Other personnel may be engaged in the activity, assisting with the dialysis support services. Survey Procedures: §405.2162(c) Review training records for evidence that the qualified nurse actively participates in patient/family training.
V440	§405.2163 Condition: Minimal service requirements for a renal dialysis facility or renal dialysis center. The facility must provide dialysis services as well as adequate laboratory, social, and dietetic services to meet the needs of the ESRD patient.	Interpretive Guidelines: §405.2163 These services can be furnished either directly or through a contractual relationship. To be certified as an ESRD supplier, a dialysis facility must provide outpatient treatments. A renal dialysis center, i.e., a hospital that can adequately treat ESRD patients, must be able to provide dialysis services to an ESRD patient when admitted. Inpatient treatments to hospitalized patients are covered under the hospital's Medicare provider number.
V441	(a) Standard: Outpatient dialysis services-- (1) Staff-assisted dialysis services. The facility must provide all necessary institutional dialysis services and staff required in performing the dialysis.	§405.2163(a)(1)
V442	(2) Self-dialysis services. If the facility offers self-dialysis services, it must provide all medically necessary supplies and equipment and any other service specified in the facility's patient care policies.	§405.2163(a)(2)

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
V443	(b) Standard: Laboratory services. The dialysis facility makes available laboratory services (other than the specialty of tissue pathology and histocompatibility testing), to meet the needs of the ESRD patient. All laboratory services must be performed by an appropriately certified laboratory in accordance with part 493 of this chapter. If the renal dialysis facility furnishes its own laboratory services, it must meet the applicable requirements established for certification of laboratories found in part 493 of this chapter.	Interpretive Guidelines: §405.2163(b) Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), laboratory services can only be provided by an appropriately certified laboratory. Arrangements with these providers must be in writing and signed, and should specify the types of laboratory tests to be performed and their frequency, methods for collection and delivering results. Facilities furnishing their own laboratory services usually perform only waived tests under CLIA, i.e., spun microhematocrits and fingerstick blood glucoses obtained by glucose monitoring devices cleared by FDA specifically for home use, and should have a CLIA certificate of waiver. A few may perform activated clotting times (ACT) and should have a "regular" CLIA certificate (certificate of compliance) or CLIA certificate of accreditation which allows the legal performance of tests of moderate complexity.
V444	If the facility does not provide laboratory services, it must make arrangements to obtain these services from a laboratory certified in the appropriate specialties and subspecialties of service in accordance with the requirements of part 493 of this chapter.	Interpretive Guidelines: §405.2163(b) There should be documentation in the patient's record that all laboratory tests prescribed were furnished as ordered. Laboratory reports should include the name and address of the laboratory performing the test. Tests for clotting time (ACT) do not fall under the certificate of waiver and must be performed by a facility with a CLIA certificate to conduct tests of moderate complexity.
V445	(c) Standard: Social services. Social services are provided to patients and their families and are directed at supporting and maximizing the social functioning and adjustment of the patient.	§405.2163(c)

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
V446	Social services are furnished by a qualified social worker (§405.2102) who has an employment or contractual relationship with the facility.	Interpretive Guidelines: §405.2163(c) A "qualified social worker" as defined in §405.2102 is a person who is licensed, if applicable, by the State in which practicing, and (1) Has completed a course of study with specialization in clinical practice at, and holds a masters degree from a graduate school of social work accredited by the Council on Social Work Education; or (2) Has served for at least 2 years as a social worker, 1 year of which was in a dialysis unit or transplantation program prior to September 1, 1976, and has established a consultative relationship with a social worker who qualifies under paragraph (1) of this definition. The social worker may be an employee of the facility or have a contractual relationship with the facility.
V447	The qualified social worker is responsible for conducting psychosocial evaluation, participating in team review of patient progress and recommending changes in treatment based on the patient's current psychosocial needs, providing casework and group work services to patients and their families in dealing with the special problems associated with ESRD, and identifying community social agencies and other resources and assisting patients and families to utilize them.	§405.2163(c)
V448	(d) Standard: Dietetic services. Each patient is evaluated as to his nutritional needs by the attending physician and by a qualified dietician (§405.2102) who has an employment or contractual relationship with the facility.	Interpretive Guidelines: §405.2163(d) A "qualified dietitian" as defined in §405.2102 is a person who (1) Is eligible for registration by the American Dietetic Association under its requirements in effect on June 3, 1976, and has at least 1 year of experience in clinical nutrition; or (2) Has a baccalaureate or advanced degree with major studies in food and nutrition or dietetics, and has at least 1 year of experience in clinical nutrition. The dietitian may be an employee of the facility or have a contractual relationship with the facility.
V449	The dietitian, in consultation with the attending physician, is responsible for assessing the nutritional and dietetic needs for each patient, recommending therapeutic diets, counseling patients and their families on prescribed diets, and monitoring adherence and response to diets.	§405.2163(d)

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
V450	(e) Standard: Self-dialysis support services. The renal dialysis facility or center furnishing self-dialysis training upon completion of the patient's training, furnishes (either directly, under agreement or by arrangement with another ESRD facility) the following services: (1) Surveillance of the patient's home adaptation, including provisions for visits to the home or the facility;	Interpretive Guidelines; §405.2163(e)(1) This standard describing self dialysis support services covers both home hemodialysis and peritoneal dialysis, including continuous ambulatory peritoneal dialysis (CAPD) and continuous cycling peritoneal dialysis (CCPD). The facility must provide periodic monitoring of the self-dialysis patient in the facility or at home, and the care plan must include this provision. Continued evaluation of the home environment and the patient's suitability for home dialysis must be reflected in periodic reviews of the care plan.
V451	(2) Consultation for the patient with a qualified social worker and dietitian;	Survey Procedures and Probes: §405.2163(e)(2) Interview home patients by phone or in person. Ask how services are provided by the social worker and dietitian.
V452	(3) A recordkeeping system which assures continuity of care;	Survey Procedures and Probes: §405.2163(e)(3) The patient's daily records should be adequately maintained and up to date. There should be documentation in the records showing that all required support services are being furnished to the self-dialysis patient.
V453	(4) Installation and maintenance of equipment;	Interpretive Guidelines: §405.2163(e)(4) Machine maintenance contracts can be between the patient and the facility or between the patient and the manufacturer. Survey Procedures and Probes: §405.2163(e)(4) The records should show that the facility's technical personnel evaluated the patient's ability to maintain the efficiency of the equipment (including water treatment equipment). Determine what support services are provided by the facility for mechanical assistance. Ask the home patient what happens if his/her machine/cycler breaks down.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
V454	(5) Testing and appropriate treatment of the water; and	Survey Procedures and Probes: §405.2163(e)(5) Review the results of water quality testing for the home patient.
V455	(6) Ordering of supplies on an ongoing basis.	§405.2163(e)(6)
V456	(f) Standard: Participation in recipient registry. The dialysis facility or center participates in a patient registry program with an OPO designated or redesignated under part 485, subpart D of this chapter for patients who are awaiting cadaveric donor transplantation.	Interpretive Guidelines; §405.2163(f) Each ESRD facility must participate in a patient registry program to ensure that patients who choose transplantation as a favorable modality and who do not have a living related donor may be matched to a non-related cadaveric donor organ. Survey Procedures and Probes: §405.2163(f) How does the facility ensure that appropriate patients are listed with a transplant registry?
V457	(g) Use of EPO at home: Patient selection. The dialysis facility, or the physician responsible for all dialysis-related services furnished to the patient, must make a comprehensive assessment of the patient that includes the following: (1) Pre-selection monitoring. The patient's hematocrit (or hemoglobin), serum iron, transferrin saturation, serum ferritin, and blood pressure must be measured.	Interpretive Guidelines: §405.2163(g) The definition of "home dialysis patient" includes both the hemodialysis and peritoneal dialysis home patient. The safe and effective use of erythropoietin (EPO) by patients at home requires that the patient's dialysis facility or physician responsible for all dialysis-related services make a comprehensive assessment of the patient and the patient's needs at the time of selection for EPO therapy. The assessment should include a determination about whether the patient is able to administer the drug, and if not, whether the patient has available the necessary assistance from a caregiver. Survey Procedures: §405.2163(g) Review records of home patients on EPO. Look for documentation of teaching related to these requirements.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
V458	2) Conditions the patient must meet. The assessment must find that the patient meets the following conditions: (i) On or after July 1, 1991, is a home dialysis patient or, on or after January 1, 1994, is a dialysis patient; (ii) Has a hematocrit (or comparable hemoglobin level) that is as follows: (A) For a patient who is initiating EPO treatment, no higher than 30 percent unless there is medical documentation showing the need for EPO despite a hematocrit (or comparable hemoglobin level) higher than 30 percent. (Patients with severe angina, severe pulmonary distress, or severe hypertension may require EPO to prevent adverse symptoms even if they have higher hematocrit or hemoglobin levels.) (B) For a patient who has been receiving EPO from the facility or the physician, between 30 and 33 percent.	Interpretive Guidelines: §405.2163(g)(2)(ii) The "comparable hemoglobin level" for a hematocrit of less than 30 percent is a hemoglobin of less than 10 percent. Survey Procedures: §405.2163(g)(2)(ii) Review the records of patients receiving EPO at home to determine if they meet the conditions stipulated in the regulations. *Note: FDA labelling for EPO was raised from 30-33 to 30-36. Clarifying instructions were issued to claims processors; however, regulations here have not been revised. As a practical matter, administration of EPO to patients with hematocrits up to 36 percent would be in compliance with current expectations.*
V459	(iii) Is under the care of-- (A) a physician who is responsible for all dialysis-related services and who prescribes the EPO and follows the drug labeling instructions when monitoring the EPO home therapy; and (B) A renal dialysis facility that establishes the plan of care and monitors the progress of the home EPO therapy.	§405.2163(g)(2)(iii)

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
V460	(3) Conditions the patient or the patient's caregiver must meet. The patient or caregiver who assists the patient in performing self-dialysis, must meet the following conditions: (i) Is trained by the facility to inject EPO and capable of carrying out the procedure. (ii) Is capable of reading and understanding drug labeling. (iii) Is trained in, and capable of observing, aseptic techniques.	Survey Procedures and Probes: §405.2163(g)(3) Interview patients who receive EPO at home. Ask how they were taught to administer the drug. Ask if they are able to give the injection themselves or who helps them. Ask them if they understand the side effects of the drug. Ask how frequently they have laboratory tests done to monitor the effects of the drug. What evidence is there to indicate that the patient or patient's caregiver has been sufficiently trained to ensure that he/she is capable of reading and understanding drug labeling and self-administering the drug? Ask patients if they feel confident in self-administering their erythropoietin.
V461	(4) Care and storage of drug. The assessment must find that EPO can be stored in the patient's residence under refrigeration and that the patient is aware of the potential hazard of a child's having access to the drug and syringes.	Survey Procedures: §405.2163(g)(4) Determine that there is a written protocol to guide the patient on the home use of EPO.
V462	(h) Use of EPO at home: Responsibilities of the physician or the dialysis facility. The patient's physician or dialysis facility must-- (1) Develop a protocol that follows the drug label instructions; (2) Make the protocol available to the patient to ensure safe and effective home use of EPO; and (3) Through the amounts prescribed, ensure that the drug "on hand" at any time does not exceed a 2-month supply.	§405.2163(h) Survey Procedures; §405.2163(h)(3) Determine what quantity of EPO is delivered to patients using EPO at home.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	§405.2164 Conditions for Coverage of special purpose renal dialysis facilities. (a) A special purpose renal dialysis facility must comply with all conditions for coverage for renal dialysis facilities specified in §§405.2130 through 405.2164, with the exception of §§405.2134 and 405.2137 that relate to participation in the network activities and patient long-term programs.	§405.2164(a)
	(b) A special purpose renal dialysis facility must consult with a patient's physician to assure that care provided in the special purpose dialysis facility is consistent with the patient's long-term program and patient care plan required under §405.2137.	§405.2164(b)
	(c) The period of approval for a special purpose renal dialysis facility may not exceed 8 calendar months in any calendar year.	§405.2164(c)
	(d) A special purpose renal dialysis facility may provide services only to those patients who would otherwise be unable to obtain treatments in the geographical areas served by the facility.	§405.2164(d)

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
V480	§405.2170 Condition: Director of Transplantation Center The renal transplantation center is under the general supervision of a qualified transplantation surgeon (§405.2102) or a qualified physician-director (§405.2102), who need not serve full time.	Interpretive Guidelines: §405.2170 A "qualified transplantation surgeon " as defined in §405.2102 is a person who (1) Is board eligible or board certified in general surgery or urology by a professional board; and (2) Has at least 12 months training or experience in the performance of renal transplantation and the care of patients with renal transplants. A "qualified physician-director " as defined in §405.2102 is a person who (1) Is board eligible or board certified in internal medicine or pediatrics by a professional board, and has had at least 12 months of experience or training in the care of patients at ESRD facilities; or (2) during the 5-year period prior to September 1, 1976 served for at least 12 months as director of a dialysis or transplantation program; or (3) In those areas where a physician who meets the definition in paragraph (1) or (2) of this definition is not available to direct a participating dialysis facility, another physician may direct the facility, subject to the approval of the Secretary.
V481	This physician is responsible for planning, organizing, conducting, and directing the renal transplantation center and devotes sufficient time to carry out these responsibilities, which include but are not limited to the following: (a) Participating in the selection of a suitable treatment modality for each patient.	§405.2170(a)

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
	Patients are accepted for transplantation only on the order of a physician and their care continues under the supervision of a physician.	
V491	(a) Standard: Participation in Recipient Registry The renal transplantation center participates in a patient registry program with an OPO certified or recertified under part 485, subpart D of this chapter for patients who are awaiting cadaveric donor transplantation.	Survey Procedures: §405.2171(a) Review the written agreement with an Organ Procurement Organization (OPO).
V492	(b) Standard: Social Services Social services are provided to patients and their families and are directed at supporting and maximizing the social functioning and adjustment of the patient. Social services are furnished by a qualified social worker (§405.2102) who has an employment or contractual relationship with the facility.	Interpretive Guidelines: §405.2171(b) A "qualified social worker" as defined in §405.2102 is a person who is licensed, if applicable, by the State in which practicing, and (1) Has completed a course of study with specialization in clinical practice at, and holds a masters degree from a graduate school of social work accredited by the Council on Social Work Education; or (2) Has served for at least 2 years as a social worker, 1 year of which was in a dialysis unit or transplantation program prior to September 1, 1976, and has established a consultative relationship with a social worker who qualifies under paragraph (1) of this definition. The social worker may be an employee of the facility or have a contractual relationship with the facility. Survey Procedures and Probes: §405.2171(b) Social services should be available to transplant recipients without the need for a physician's order. Look for evidence that social services are provided on your review of transplant recipients' records. How does the transplant service notify the social worker of the admission of a patient?

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
V493	The qualified social worker is responsible for conducting psychosocial evaluations, participating in team review of patient progress and recommending changes in treatment based on the patient's current psychosocial needs, providing casework and groupwork services to patients and their families in dealing with the special problems associated with ESRD, and identifying community social agencies and other resources and assisting patients and families to utilize them.	Survey Procedures; §405.2171(b) Interview patients regarding assistance/counseling provided by the transplant center's social worker.
V494	(c) Standard: Dietetic Services. Each patient is evaluated as to his nutritional needs by the attending physician and a qualified dietician (§405.2102) who has an employment or contractual relationship with the facility.	Interpretive Guidelines: §405.2171(c) A "qualified dietitian" as defined in §405.2102 is a person who (1) Is eligible for registration by the American Dietetic Association under its requirements in effect on June 3, 1976, and has at least 1 year of experience in clinical nutrition; or (2) Has a baccalaureate or advanced degree with major studies in food and nutrition or dietetics, and has at least 1 year of experience in clinical nutrition. The dietitian may be an employee of the facility or be in a contractual relationship with the facility. Survey Procedures and Policies: §405.2171(c) Is there a qualified dietitian assigned responsibility for transplant patients?
V495	The dietitian, in consultation with the attending physician, is responsible for assessing the nutritional and dietetic needs of each patient, recommending therapeutic diets, counseling patients and their families on prescribed diets, and monitoring adherence and response to diets.	Survey Procedures; §405.2171(c) Review records and interview patients regarding the appropriateness and timeliness of nutritional counseling. Patients' nutritional needs/problems change post-transplant (e.g., less concern with fluids, more concern with concentrated sweets and weight gain). Observe that these changes are addressed by the dietitian.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
V496	(d) Standard: Laboratory Services: (1) The renal transplantation center makes available, directly or under arrangements, laboratory services to meet the needs of ESRD patients. Laboratory services are performed in a laboratory facility certified in accordance with part 493 of this chapter. (2) Laboratory services for crossmatching of recipient serum and donor lymphocytes for pre-formed antibodies by an acceptable technique are available on a 24-hour emergency basis.	Interpretive Guidelines: §405.2171(d) Laboratories performing crossmatching of recipient serum and donor lymphocytes (histocompatibility testing) must have either a "regular" CLIA certificate or certificate of accreditation, which allow them to legally perform high complexity testing.
V497	(e) Standard: Organ Procurement: A renal transplantation center using the services of an organ procurement organization designated or redesignated under part 485, subpart D of this chapter to obtain donor organs has a written agreement covering these services. The renal transplantation center agrees to notify HCFA in writing within 30 days of the termination of the agreement.	Interpretive Guidelines: §405.2171(e) Usually, one agreement with an OPO covers both the maintenance of a recipient registry and organ procurement.

APPENDIX I

INTERPRETIVE GUIDELINES
LIFE SAFETY

APPENDIX I

Interpretive Guidelines - Life Safety Code

Part I FIRE PROTECTION SURVEY PROCEDURES FOR HOSPITALS, SNFs, ICFs, ASCs AND HOSPICES

Part II SPECIAL FIRE PROTECTION SURVEY PROCEDURES FOR ICFs/MR

Part III ALERTING STATE AGENCY TO IMMEDIATE JEOPARDY

Fire Protection Survey Procedures for Hospitals, SNFs, ICFs, ASCs and Hospices

GUIDELINES FOR COMPLETION OF THE FIRE SAFETY SURVEY REPORT (HCFA-2786, Part I)

ITEM 1.
Enter the provider number for a Medicare facility, the vendor number for a Medicaid facility; both if the facility participates in both programs. In initial survey if the facility has not yet been assigned a number, leave this block blank.

ITEM 2, 2B.
Self-explanatory.

ITEM 2A.
If there is more than one building involved, or if there are multiple construction types within the building being surveyed, complete a separate survey form for each building or for each section of the building with a different construction type. Identify which buildings or portions thereof are being surveyed in Item 2A.

ITEM 3.
If the facility participates in both the Medicare and Medicaid programs, check both blocks; if the facility participates in one program, check the appropriate block.

ITEM 4.
Self-explanatory.

ITEM 5.
If the survey is for certification of a SNF or ICF, complete the portion of Item 5 below the heavy black line.

ITEM 6.
Self-explanatory.

ITEM 7.
Determining Compliance: Compliance with the Life Safety Code (LSC) can, as indicated on the Survey Report, be based upon meeting all provisions of the Code. Alternatively, if there are deficiencies, facilities can be found in compliance in consideration of waiver recommendations and/or an acceptable plan of correction. (A timely followup must be conducted in all facilities to confirm that the deficiencies have been corrected.) If the survey indicates that a facility is not in compliance with the LSC, a recommendation of certification would be inappropriate. Do not follow up visits at accredited hospitals, unless the hospital loses its "deemed" certification status.

While an accredited hospital retains its "deemed" certification status, it cannot meet the LSC based upon waiver or a plan of correction. Once "deemed" status has been removed, an accredited hospital can be found in compliance with the LSC based upon waiver or an acceptable plan of correction.

When you cannot determine compliance or consider waiver until a plan of correction is received, defer completion of the compliance check blocks until the facility has had a reasonable time to submit its plan of correction. Give the facility 14-30 days from the date it is informed of its deficiencies to file its plan of correction (not necessarily to make the actual corrections within this time.) The time granted to return a plan of correction is dependent upon the nature of the deficiencies. A reasonable period of time for submission of a plan of correction where costly structural renovations are requested would not be the same as required to replace a small number of doors or to put an acceptable fire drill plan into practice. If no response is received within the allotted time, send a followup notice promptly.

When the plan of correction is received, or if no plan is received within 10 days after the followup notice was sent to the provider, indicate in Item 7 whether the facility is in compliance based on the information in file, sign the Survey Report and forward it to the State agency.

If, on a previous survey, compliance was based upon acceptance of a plan of correction and the deficiency has not been corrected by the date of the current survey, check Item 7 "Does Not Meet." If a different item is found to be deficient, a plan of correction may be accepted if you mark the HCFA-2567 "Meets, based upon an acceptable plan of correction."

Signature: The State fire authority official who signs the HCFA-2786 should be the principal official of the office conducting fire safety surveys or another official to whom this authority has been delegated. If other than the principal official, a written delegation of authority should be on file in the State agency.

K-11 to K-84 (K-numbers used herein refer to HCFA-2786 data tags).--For each item on these pages, indicate "Met" or "Not Met" or "Not Applicable". Where a "Not Applicable" response is inappropriate, that box should be shaded. For each item marked "Not Met," enter appropriate documentation in Explanatory Remarks, explaining the nature of the deficiency and the degree of hazard it represents. If there is insufficient space in Explanatory Remarks, use the back of that particular page for additional comments, and indicate the related Survey Report item number (e.g., K42, K63) so that each comment is identified. In addition, list on the Statement of Deficiencies and Plan of Correction, HCFA-2567, each item marked "Not Met"

Every effort has been made to reflect in the survey questions the intent of the LSC requirements. However, the following explanations of selective survey items should be useful in conducting the survey and completing the Survey Report.

K11 - K13, Building Construction.--The construction types listed on the Survey Report are taken directly from NFPA 220 (Building Construction). Describe non-compliant unprotected construction in REMARKS.

In wood frame and ordinary construction, protection is not required on the top side of the ceiling joist in concealed or unusable attic spaces. Fire protection of building elements or automatic sprinkler protection, however, is required where spaces are used as storage areas or for any use other than access for maintenance purposes.

Fire-retardant treated wood may be used in non-load bearing partitions if used with a wall assembly in buildings of fire-resistive and noncombustible construction which meets the definition of noncombustible set forth in
NFPA 220.

All interior walls and partitions in institutional buildings of fire resistive and noncombustible construction must be composed of noncombustible materials. Fire-retardant, pressure-impregnated wood studs may meet the specified definition of noncombustibility if they have a flame-spread rating of not more than 25 when tested in accordance with the Standard Method of Testing of Surface-Burning Characteristics of Building Materials (ASTM-E-84-68) as contained in NFPA Standard No. 255.

End of stud members that are cut after treatment to meet field conditions may be considered in compliance with Department requirements for fire resistive and noncombustible construction and interior non-load-bearing partitions if they are protected by treated wood top and bottom members.

Some buildings are constructed with wood frame roofs for reasons of snow loading or aesthetics. A building with a wood-frame roof can be classified as fire resistive if the structural wall and floor-framing assemblies are fire-resistive and a fire-resistive deck separates the upper floor from the wood-frame roof. The fire-resistive deck must be a structural slab which provides a 2-hour fire resistance and fully separates the upper floors (no holes) from roof construction members.

Ducts and pipes, which pass through fire-resistive walls, floors, or ceilings, should be properly fire stopped by packing the holes with rope asbestos or mineral wool which will prevent the passage of flame and smoke. If the space is greater than 1/2 inch, lath and plaster, brick, or cement may be needed depending upon the fire resistance of the floor, wall or roof assembly.

K17 - K19 CORRIDOR WALLS AND DOORS.--A corridor wall separating institutional sleeping rooms and treatment areas is a partition that subdivides spaces within any story of a building which is designed to restrict the spread of fire. Corridor walls must extend through any concealed spaces such as between suspended ceilings and the floor or roof above. It is acceptable for a corridor wall to extend to a continuous membrane ceiling attached directly to the structural flooring element if the membrane ceiling is a component of a floor-ceiling or roof-ceiling assembly.

Generally, building elements utilizing 1/2 inch gypsum wallboard provide no more than 3/4 hour fire resistance. The U.L. Fire Resistance Index lists a limited number of floor and wall assemblies using 1/2 inch gypsum that provide l-hour fire resistance.

A labeled 30 minute particle board core door is considered equivalent to a 1 3/4 inch solid wood bonded core door in a doorway to an institutional sleeping room. Any particle board door that meets ASTM E152-66 Standard Fire Tests of Door Assemblies with a 30-minute fire exposure, plus a 17-second hose stream immediately afterward provides equivalent fire resistance.

Rated door frame assemblies are not required in the door openings to patient rooms, nor is it required that they be provided with closers and positive latching devices required by rated fire door assemblies. A l 3/4 inch solid core wood door is not a fire door and does not require a rated frame. Friction roller latches on such doors would be acceptable.

K23 - K28, SMOKE COMPARTMENTATION AND CONTROL.--The subdivision of patient sleeping floors by smoke stop partitions or horizontal exits into two or more compartments or fire sections is not based upon the cumulative connected corridor length of no more than 150 feet. It is intended that the provision will limit the gross floor area of a compartment as well as the length and width of each compartment on patient sleeping room floors to dimensions not exceeding 150 feet, or 22,500 square feet. (1981 LSC.)

K56 - K63, SPRINKLER COVERAGE.--To be in compliance with the LSC, a sprinkler system must be installed in accordance with NFPA Standard No. 13. The Department has required that the Contractor's Material and Test Certificate for Sprinkler System identified in the standard be available in the facility as documentation that the system was installed in accordance with Standard No. 13. If Item K56 is marked "Not Applicable" because the building is a fire-resistive or is a one story protected noncombustible structure, then mark Items K59 to K63 "Not Applicable."

K51 MANUALLY OPERATED FIRE ALARM SYSTEM.--It is not mandatory that the fire alarm system be electrically supervised in existing buildings. This is desirable, but the LSC only requires electrical supervision of the fire alarm systems in new buildings. The fire alarm must automatically transmit a alarm to the fire department or an outside service in both New and Existing buildings under the 1981 LSC.

K50 FIRE DRILLS.--A total of 12 fire drills per year are required, not 12 on each shift. They should be held in such a manner as to familiarize employees on all shifts with fire drill procedures.

GUIDELINES FOR COMPLETION OF THE
FIRE SAFETY SURVEY REPORT, HCFA-2786, Part II

PAGE 10.
Under certain circumstances, section 1861(j)(13) of the Social Security Act permits waivers of specific provisions of the LSC that would impose unreasonable hardship on an institution. The provisions in Part II of the HCFA-2786 are program requirements (Title 42, Sections 405.1022(b) and 405.1134(a) of the Code of Federal Regulations), not identified in the LSC and, as indicated on the Survey Report, are not waiverable.

K78, Anesthetizing Areas.--This item pertains to HOSPITALS only. If surveying a SNF or ICF, indicate NOT APPLICABLE.

Verify that conductive flooring in anesthetizing locations complies with section 252 of National Fire Protection Association (NFPA) Reference Pamphlet 56A (Inhalation Anesthetics). If no flammable anesthetics are used, flooring need not be conductive. Requirements formerly specified by NFPA 56A, inhalation anesthetics, are now contained in NFPA 99, Health Facilities Code. NFPA 99 requires isolated power only in flammable anesthetizing areas or wet locations. Grounding systems need not be equipotential, but must be
installed and maintained in each anesthetizing location with an isolation transformer to minimize the difference in potential which can occur between any conductive surface that the patient or a person touching the patient can contact.

The hospital must be able to demonstrate that the voltage differential under these conditions is less than 5 millivolts. Certification from a consultant electrical engineer or a firm which conducts such tests is acceptable; however, the hospital may utilize its own personnel if tests are conducted in line with the following procedures:

Voltage Differential Measurements

1. Voltage differential measurements should be made between all ground
points (includes receptacle ground poles and separate grounding jacks where installed) in the anesthetizing area. Measurements should also include conductive surfaces within 6 feet of the operating table.

2. Voltmeter shall have a minimum of 500 ohms at 60 hz. Meters with
5000 ohms or more impedance may be used in conjunction with a 500 ohm resistor. If the voltmeter or test instrument is line operated, both test prods must be isolated from ground. Assuming a measurement from point A to B, connect the resistor across the two points, in parallel with the voltmeter leads.

3. Prior to conducting these test procedures:

o. Verify continuity of the grounding system.

o. Determine that the circuits under test are supplied from an isolated system and that the system is ungrounded.

Tests shall be made with all operating rooms supplied from the isolated system shut down, and fixed equipment energized.

4. Two voltage measurements shall be made across each pair of ground points. The first measurement with the isolated system in normal condition; the second with the isolated system intentionally shorted from one energized conductor to ground. Do not short both energized conductors.

5. The general procedure shall be as follows:

o. Prepare a small scale sketch of the anesthetizing area with each ground point identified by letter.

o. Select the grounding pole of the receptacle nearest the head of the operating table as a reference point and measure the voltage differential to each of the other ground points. For this measurement, the isolated system shall be in the normal condition.

o. Repeat the measurements in Item b, except with the isolated system shorted from one energized conductor to ground. This intentional ground should be applied at the reference receptacle noted in Item b.

o. Tabulation of the voltage measurements shall be similar to the following:

Ground Points	System Normal	System Shorted
A - B	2 MV	2 MV
A - C	2	2
A - D	5	5
A - E	3	4
A - F	4	4
A - G	4	4

6. The hospital shall furnish the surveyor the following information:

   o Sketch noted in 5a.

   o Tabulation of test results noted in 5d.

   o Voltmeter identification including impedance at 60 hz; was 500 ohm resistor used?

   o Signed statement that the system has been tested in accordance with these guidelines and performs in accordance with the appropriate regulations.

NOTE A. Emergency rooms in which no surgical procedures using inhalation anesthetics are performed are not included under these requirements.

NOTE B. Corridors or utility rooms, unless specifically designated as anesthetizing areas, are not included under these requirements.

K-79.--This applies only to SNFs and ICFs. Indicate NOT APPLICABLE, regardless of construction type.

K80 - K83, Alternative Provisions to Sprinkler Requirements.--Complete this section if Item K56 is marked "NOT MET" and the facility is an unsprinklered or partially sprinklered one-story protected wood frame facility. Completion of this section is optional for other types of construction. If Item K56 is marked "Not Applicable" (see Item K56 "Sprinkler Coverage") leave Part III A blank.

There can be no waiver of the sprinkler requirement for unprotected wood frame facilities or multi-story wood frame facilities whether protected or not.

Note that each of the four equivalency criteria (see §3192) must be met before a waiver of the sprinkler requirement in one-story wood frame facilities is granted. Waivers for this type of construction CANNOT be granted based upon the acceptance of a plan of correction. You must verify that the corrections were actually made, e.g., that smoke detectors were installed, before recommending a waiver.

When recommending waiver on the basis of correction of another deficiency, do not grant the waiver until the action on the other item is completed. For example, if you propose to waive the installation of return air ducts where corridors are being used as return air plenums, and also recommend that the facility install detectors tied into an alarm system and automatic shutdown

of fans, do not waive the return air plenums until you verify that the facility has actually installed the detectors which are appropriately connected to the alarm and air circulation system.

In the above cases, the first page of the HCFA-2786 should be marked, "Meets, based upon acceptance of a plan of correction." Only after the corrections have been completed can the form be marked, "Meets, based upon recommended waivers . . ."

When a plan of correction contemplates meeting the equivalency criteria, mark the facility in compliance based upon acceptance of a plan of correction. If the correction is satisfactorily completed, a waiver of the sprinkler requirement based upon meeting the equivalency criteria may be issued.

Part IIIA MUST be completed for one story unsprinklered or partially sprinklered protected wood frame facilities. Completion of Part IIIA is optional in all other cases. While the information is relevant to a decision concerning waiver of the sprinkler requirement in other types of construction, all four criteria MUST be met for a waiver of the sprinkler requirement in one-story protected wood frame facilities.

K84, Waiver Recommendation.--For each item recommended for waiver, list the Survey Report item number and indicate:

- How compliance would impose an unreasonable hardship on the facility; and
- How waiver would not adversely affect the health and safety of patients in the facility.

When waiver is recommended, both the surveyor and the concurring fire authority official must sign the form at the bottom of page 12. Recommendation of waiver may be completed only after the provider has responded to the Statement of Deficiencies. See §3190 for more detailed instructions regarding waivers.

Building Sketch
If there are no multiple construction types, and there are no unusual design features or construction deficiencies, completion of the building sketch is optional. If more than one type of construction is used, show dates of each addition and types of construction. Indicate portions of buildings where unusual design features or construction deficiencies exist, e.g., dead end corridors.

ADDENDUM TO THE 1985 LIFE SAFETY CODE

When surveying for compliance with the 1985 Life Safety (LSC) Code:

- Use the 1981 LSC survey form HCFA-2786F;
- Indicate "1985 LSC" in the remarks column; and
- Cite the 1985 LSC references in parentheses below.

K-13 NEW - Any construction, over 75 feet in height, must be fully-sprinklered. (12-3.5.1)

K30 (1) - Gift Shops - New and existing gift shops shall be protected as a hazardous area when used for storage or display of combustibles in quantities considered hazardous. (12-3.2.3, 13-3.2.3)

K-51 EXISTING - Fixed extinguishing systems protecting commercial cooking equipment in kitchens protected by a complete automatic sprinkler system need not initiate the building fire alarm system. (13-3.4.2)

K-18 NEW AND EXISTING -

Dutch doors may be used when they conform to 12-3.6.3 or 13-3.6.3 and in addition, both upper leaf and lower leaf shall be equipped with a latching device and the meeting edge of the upper and lower leaves shall be equipped with an astragali, rabbet, or bevel.

Dutch doors protecting openings in enclosures around hazardous areas shall comply with NFPA 80, Standard for Fire Doors and Windows. (12.3.6.4, 13-3.6.4)

K-21 NEW - Includes stairway doors. Initiation of a door closing action on any level shall cause all doors at all levels in the stair enclosure to close. (12-2.11.5, 12-2.11.6)

K-24 NEW AND EXISTING -

One dimension may be extended provided that the total width plus length does not exceed 300 feet and provided that the travel distance from a room to a smoke barrier door or horizontal exit is no more than 150 feet. (12-3.7.1, 13-3.7.1)

K-25 NEW AND EXISTING -

When an atrium is used, smoke barriers may terminate at an atrium wall. A minimum of two separate smoke compartments shall be provided on each floor. (12-3.7.3, 13-3.7.3)

DDENDUM TO THE 1985 LIFE SAFETY CODE

K-55 NEW AND EXISTING -

Windows opening into atriums when the atriums have a smoke removal system are, for the purposes of this requirement, considered outside windows. (12.3.8.1, 13-3.8.1)

K-31 NEW AND EXISTING -

Egress may be through adjacent compartment(s), but shall not require return through the compartment of fire origin. (12-2.4.3, 13-2.4.3, 12-2.4.2, 13-2.4.2)

K-38 NEW ONLY - A maximum of 50 percent of the required exists may discharge through areas on the floor of exit discharge in accordance with (5-7.2).

PART TWO

Fire Protection Survey Procedures for ICFs/MR

I. HOW TO DETERMINE APPLICABLE LIFE SAFETY CODE CHAPTER

A. Personal Care Services - ICFs/MR Subject to Chapter 21.--The first determination to be made when surveying any building for compliance with the Life Safety Code is which occupancy chapter to use. The Residential Board and Care Occupancy chapter (Chapter 21) of the 1985 edition of the LSC is applicable to ICFs/MR in the Medicaid program which provide "personal care services." The LSC defines personal care as "protective care of a resident who does not require chronic or convalescent medical or nursing care."

Generally, protective oversight and personal care is a form of assistance in meeting daily needs (e.g., being aware of resident's whereabouts, reminding them of appointments). This may include "transient medical care," which is the kind of care provided in the home by one family member to another when he/she is sick. In an ICF/MR this means supervising client's movements and daily living skills. On the other hand, skilled or acute nursing or medical care such as is provided in a hospital or nursing home would necessitate the use of Chapter 12 or 13 (Health Care Occupancies). An RN or LPN on staff at the board and care home solely to dispense medication is not an indication of chronic medical or nursing care. Most large facilities fall into the category of health care, while smaller facilities tend to be residential board and care occupancies.

B. Chronic or Convalescent Care - ICFs/MR Subject to Chapters 12 and 13.--If a resident receives chronic or convalescent medical or nursing care, the facility is classified for LSC purposes as a health care occupancy and must be surveyed under the Health Care chapter (12 or 13).

II. RATING THE FACILITY

A. Determinations Under Chapter 21.--Once it is determined that an ICF/MR is a Residential Board and Care Occupancy under Chapter 21, two determinations must be made in order to proceed with the survey and certification of the facility; size of facility and level of evacuation capability. All of the fire protection requirements of Chapter 21 are based upon an assessment of these two factors.

1. Size of Facility: Chapter 21 is divided into 4 sections:

   - Section 21-1: Introduction and General Requirements.

   - Section 21-2: Small Facilities - Sleeping accommodations for not more than 16 residents.

- o Section 21-3: Large Facilities - Sleeping accommodations for more than 16 residents.

- o Section 21-4: "Suitability of an Apartment Building to House a Board and Care Occupancy."

Survey each facility under Section 21-1 to determine if the ICF/MR is indeed a board and care occupancy, and then proceed to the appropriate section (Small, Large or Board and Care facility in Apartment House) as indicated in the definitions above.

2. Level of Evacuation Difficulty--Each of the sections in 1 above, (small, large and Board and Care facility in an apartment house) is divided into three sections with requirements based on level of evacuation difficulty. The three levels of evacuation difficulty are known as Prompt (Level A), Slow (Level B), and Impractical (Level C). Use the Evacuation Difficulty Index (EDI) of Appendix F of the Life Safety Code - "A Procedure for Determining Evacuation Difficulty" to determine the level of the facility.

3. How to Determine the "E Score".--In order to determine the "E score", complete the six worksheets in the following manner (see Exhibit 1):

a. F-1 - Side 1 - Worksheet for Rating Residents, HCFA-2786M.--This is a cover sheet which contains space for explanatory remarks. Enter the resident's name, your name, the name of the facility, and the date of survey and proceed to the next sheet.

b. F-1 - Side 2 -Worksheet for Rating Residents, F-1A - Rating the Resident Risk Factors, HCFA-2786M, back.--Interview the staff member who is familiar with the resident's risk factors. Rate the resident on each of the six risk factors (Risk of Resistance, Impaired Mobility, Impaired Consciousness, Need for Extra Help, Response to Instructions, and Waking Response to Alarm) by checking the appropriate circle on each line. Then write the score for each circle checked in the boxes in the far right column. For the seventh parameter (Response to Fire Drills) write the checked scores in the three large circles. Write the sum of the three scores in the box to the right.

NOTE: In a small facility complete HCFA-2786M for each resident.

c. F-1B - Finding the Resident's Overall Need for Assistance.--Compare the seven score boxes in F-1A and write the HIGHEST score in the box labeled "Evacuation Assistance Score."

d. F-2 - Worksheet For Calculating Evacuation Difficulty Score (E-Score).--Answer the five questions on this page. All five must be answered YES to satisfy the requirements for obtaining an E-Score.

e. F-2A - Finding the Total Resident Score.--List each resident's name and score in the Scoresheet (F-2A) and total the individual scores. Enter the total at the bottom in the box to right of the word TOTAL.

f. F-2B - Finding the Staff Shift Score.--List the names of each staff member required to remain in the facility for the shift being evaluated. The shift evaluated should be the one with the highest E-Score (least staff), usually the night shift. Then enter the appropriate score for Alarm Effectiveness (as determined by the table on the lower left) for each staff member. Add the scores. Enter the total in the box marked "Total."

g. F-2C - Finding the Home's Evacuation Difficulty Score.--Complete the chart at the top by indicating the vertical distance of bedrooms (that is, number of stories) from exits. Proceed to scoresheet F-2C - Calculation of E-Score. Enter the resident total score and vertical distance score in the 2 boxes which compose the numerator of this fraction and multiply them by each other. Enter the Staff Shift Score in the denominator and divide this into the product of the numerator (the answer you got by multiplying the total resident score by the vertical distance of bedrooms to exit). This is the E-Score.

h. F-2D - Evacuation Difficulty Score.--Using the chart at the bottom, enter the level of evacuation difficulty in the box at the bottom right. A score equal to or less than 1.5 is PROMPT. A score greater than 1.5 but not more than 5 is SLOW. A score of greater than 5 is IMPRACTICAL. Transfer the score to the cover page of the Survey Report, HCFA-2786 J, K or L.

B. Health Facilities Surveyor Corroborates E-Score.--The health facilities surveyor visits a facility subsequent to the fire authority's visit. During the course of the health survey, the health facilities surveyor observes clients, reviews records and interviews staff as part of the assessment of active treatment, and completes Items I through VI on the "Worksheet for Rating Residents" for each client included in his or her sample.

The purpose of having the health facilities surveyor complete a copy of the worksheet is to corroborate the findings of the fire authority obtained through interviews with staff. This is done to determine if there is any cause to question the validity of staff reports of predicted client behavior. The health facilities surveyor is not required to complete all of the forms or even calculate the Evaluation Difficulty Index. The surveyor simply completes items I to VI.

If there is a pattern of discrepancies through the items for one client or through all of the clients in the sample for one or more items, the State agency cannot certify the facility until the discrepancies are reconciled. Both the fire authority and the State agency must be satisfied that the EDI score is representative of client capability. If there are irreconcilable differences, it may be necessary to conduct a fire drill and observe and record client behavior.

III. RATING THE BUILDING

After you determine the Size of Facility and the Level of Evacuation Difficulty, rate the building. There are two alternative methods of rating the building:

1. Use the prescriptive requirements in the appropriate section of Chapter 21; or

2. Use LSC Appendix G - A Fire Safety Evaluation System for Board and Care Facilities (FSES/BC).

IV. FORMS COMPLETION AND CERTIFICATION

A. Survey Under Chapter 21.--If the prescriptive requirements of Chapter 21 are selected, complete the Fire Safety Report-Chapter 21, HCFA 2786-J, K, or L, as well as the Worksheets for Rating Residents, Staff and Determining the E-Score of the group from LSC Appendix F. In addition, complete a Statement of Deficiencies and Plan of Correction, HCFA 2567, in the usual manner (see §2728), if deficiencies are found.

B. Survey Under FSES/BC LSC Appendix G).--After you have arrived at an Evacuation Difficulty Score for the facility, you may apply the FSES/BC, LSC Appendix G, rather than the prescriptive requirements of Chapter 21. Please note that the entire Survey Report must also be completed when applying the FSES/BC. This is no different from the usual survey procedure for health care facilities. Complete a HCFA-2786-J, K, or L, along with the FSES/BC worksheets which are part of the form, for each facility certified as a Residential Board and Care Occupancy.

C. Multiple Buildings or Parts of Buildings on Campus --Many facilities house clients in more than one building. In such cases, rate each building separately. On a large campus, such as a State School for the Retarded or State Developmental Center, a large building may be surveyed under Chapter 13, Health Care, and a small building may be surveyed as a Residential Board and Care Facility under Chapter 21. In some cases, buildings may be divided into separate wings, with one wing housing Residential Board and Care occupants and the other wing housing Health Care patients. You may use different chapters for different wings if there is a 2-hour fire wall separating the two parts.

D. Large Buildings Previously Meeting Health Care Requirements.--A facility of 17 beds or more which currently meets the health care provisions of the Life Safety Code, can continue to be surveyed either under the Health Care Chapter or the FSES/Health Care. If the large facility qualifies as a Residential Board and Care occupancy, it also may opt to be surveyed under Health Care.

E. PLAN OF CORRECTION UNDER THE FSES/BC.--If the facility is to be certified based upon achieving a passing score on the FSES/BC, complete a Statement of Deficiencies, HCFA-2567, under both the regular Survey Report and the FSES/BC for any deficiencies found. The provider will indicate whether it chooses to correct the deficiencies on the HCFA-2786, or the deficiencies on the FSES/BC.

PART THREE

ALERTING STATE AGENCY TO IMMEDIATE JEOPARDY

A. Explanation of Immediate Jeopardy.--Immediate jeopardy is the existence of serious and life-threatening deficiencies which are an immediate threat to life. Some examples of life threatening deficiencies are failure to maintain required fire protection systems in an operating condition, obstructed passageways that prevent egress in the event of an emergency, open stairways, and unprotected wood frame construction which is not sprinklered.

Although the fire authority actually conducts the survey of the ICF/MR, it is the State agency which makes a determination of immediate jeopardy. If you find a situation that presents immediate jeopardy, mark Item 7 on the front of the HCFA-2786, DOES NOT MEET. If you mark MEETS WITH ACCEPTABLE PLAN OF CORRECTION, the State agency can make no finding of immediate jeopardy.

B. Immediate Jeopardy May Depend on Classification of the Residents.--Findings of immediate jeopardy will be rare in smaller ICFs/MR surveyed under Chapter 21. This is because the determination whether the facility MEETS the LSC is dependent upon 3 factors: the resident capability, the staff, and the building. The nature of Chapter 21 is such that by adding staff or by replacing incapable with capable residents promptly, the facility could be certified at a higher level of evacuation capability.

For instance, a facility which would have to be sprinkled because all the residents are incapable, could add staff to the night shift or add capable residents instead of installing sprinklers. This would reclassify it from IMPRACTICAL to SLOW and sprinklers would no longer be required. The change to a higher level of evacuation capability may obviate the need for additional fire protection features, the lack of which would have been the basis for a finding of immediate jeopardy.